

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 _____) Case No.
8) 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 TUESDAY, DECEMBER 11, 2018

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of Cathy
18 Stewart, held at the offices of STINSON
19 LEONARD STREET LLP, 7700 Forsyth Boulevard,
20 Suite 1000, St. Louis, Missouri, commencing
21 at 9:03 a.m., on the above date, before
22 Carrie A. Campbell, Registered Diplomat
23 Reporter and Certified Realtime Reporter.

24 - - -

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Page 2	Page 4
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Page 3	Page 5
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Highly Confidential - Subject to Further Confidentiality Review

Page 6		Page 8	
1	Mallinckrodt DEA Compliance Procedure, 179	1	Mallinckrodt E-mail(s), 284
2	Stewart 15 Draft 4 Published 07/15/08, MNK-TI_0000420019 -	2	Stewart 40 MNK-TI_0000449552 -
3	Mallinckrodt E-mail(s), 189	3	Mallinckrodt E-mail(s), 287
4	Stewart 16 MNK-TI_0000301990	4	Stewart 41 MNK-TI_0003037286
5	Mallinckrodt E-mail(s), 191	5	Mallinckrodt E-mail(s), 289
6	Stewart 17 MNK-TI_0000419874 -	6	Stewart 42 MNK-TI_0003025905 -
7	Mallinckrodt E-mail(s), 192	7	Mallinckrodt E-mail(s), 291
8	Stewart 18 MNK-TI_0000391444 -	8	Stewart 43 MNK-TI_0000968496 -
9	Mallinckrodt E-mail(s), 194	9	Mallinckrodt E-mail(s), 292
10	Stewart 19 MNK-TI_0000304544 -	10	Stewart 44 MNK-TI_0003028219 -
11	Mallinckrodt New Customer Account Set-Up 197	11	Mallinckrodt E-mail(s), 299
12	Stewart 20 Controlled Substance, Suspicious Order Monitoring Program, MNK-TI_0000420013	12	Stewart 45 MNK-TI_0000290601 -
13	Mallinckrodt E-mail(s), 199	13	Mallinckrodt E-mail(s), 301
14	Stewart 21 MNK-TI_0000274111 -	14	Stewart 46 MNK-TI_0000307120 -
15	Mallinckrodt E-mail(s), 212	15	Mallinckrodt E-mail(s), 303
16	Stewart 22 MNK-TI_0000391443	16	Stewart 47 MNK-TI_0000418851
17	Mallinckrodt E-mail(s), 215	17	Mallinckrodt E-mail(s), 305
18	Stewart 23 MNK-TI_0000302023	18	Stewart 48 MNK-TI_0000290065
19	Mallinckrodt E-mail(s), 217	19	Mallinckrodt Mallinckrodt Controlled Substance Suspicious Order Monitoring Program, 306
20	Stewart 24 MNK-TI_0000305967	20	Stewart 49 Introductory Training for Field Sales, June 5, 2008, MNK-TI_0000304563 -
21	Mallinckrodt Pharma Customer Service 222	21	Stewart 50 MNK-TI_0000304572
22	Stewart 25 Clearing Kaizen Event 30-Day Review, MNK-TI_00002906584	22	Mallinckrodt E-mail(s), 309
23	Mallinckrodt E-mail(s), 235	23	Stewart 51 MNK-TI_0002052862
24	Stewart 26 MNK-TI_0006305000	24	Mallinckrodt E-mail(s), 310
25	Mallinckrodt E-mail(s), 237	25	Stewart 51 MNK-TI_0000564481
25	Stewart 27 MNK-TI_0000473726		
Page 7		Page 9	
1	Mallinckrodt E-mail(s), 239	1	Mallinckrodt E-mail(s), 311
2	Stewart 28 MNK-TI_0000268346	2	Stewart 52 MNK-TI_0003027585 -
3	Mallinckrodt E-mail(s), 244	3	Mallinckrodt E-mail(s), 314
4	Stewart 29 MNK-TI_0000303636	4	Stewart 53 MNK-TI_0002906694 -
5	Mallinckrodt E-mail(s), 248	5	Mallinckrodt E-mail(s), 316
6	Stewart 30 MNK-TI_0000278394	6	Stewart 54 MNK-TI_0002906294 -
7	Mallinckrodt E-mail(s), 249	7	Mallinckrodt E-mail(s), 318
8	Exhibit 31 MNK-TI_0000300118	8	Stewart 55 MNK-TI_0000290570 -
9	Mallinckrodt E-mail(s), 250	9	Mallinckrodt E-mail(s), 319
10	Exhibit 32 MNK-TI_0000301439	10	Stewart 56 MNK-TI_0000290571
11	Mallinckrodt E-mail(s), 253	11	Mallinckrodt E-mail(s), 322
12	Exhibit 33 MNK-TI_0000279975 -	12	Stewart 57 MNK-TI_0000562682 -
13	Mallinckrodt Suspicious Order Monitoring Program, Dosage Products Shipments From Hobart, Activities 10/2008 through 6/2010, MNK-TI_0000477889 -	13	Mallinckrodt E-mail(s), 341
14	Mallinckrodt Suspicious Order Monitoring Program, Dosage Shipment Products in Hobart, Activities 08/2008 through 8/2010, MNK-TI_0000477893 -	14	Stewart 58 MNK-TI_0000562686
15	Mallinckrodt Suspicious Order Monitoring Program, Dosage Shipment Products in Hobart, Activities 08/2008 through 8/2010, MNK-TI_0000477900 -	15	Mallinckrodt E-mail(s), 345
16	Mallinckrodt E-mail(s), 263	16	Stewart 59 MNK-TI_0000562682 -
17	Stewart 35 MNK-TI_0000477912	17	Mallinckrodt E-mail(s), 347
18	Mallinckrodt E-mail(s), 268	18	Stewart 60 MNK-TI_0000562686
19	Stewart 36 MNK-TI_0000290583 -	19	Mallinckrodt E-mail(s), 351
20	Mallinckrodt E-mail(s), 273	20	Stewart 61 MNK-TI_0000562686
21	Stewart 37 MNK-TI_0000290621 -	21	Mallinckrodt E-mail(s), 361
22	Mallinckrodt E-mail(s), 277	22	Stewart 62 MNK-TI_0000562686
23	Stewart 38 MNK-TI_0002908302 -	23	Mallinckrodt E-mail(s), 365
24	Mallinckrodt E-mail(s), 281	24	Stewart 63 MNK-TI_0002908302 -
25	Exhibit 39 MNK-TI_0003027927	25	(Exhibits attached to the deposition.)

<p style="text-align: right;">Page 10</p> <p>1 VIDEOGRAPHER: We are now on 2 the record. My name is James Arndt. 3 I'm a videographer for Golkow 4 Litigation Services. 5 Today's date is December 11, 6 2018, and the time is 9:03 a.m. 7 This video deposition is being 8 held in St. Louis, Missouri, in the 9 matter of the National Prescription 10 Opiate Litigation, for the United 11 States District Court for the Northern 12 District of Ohio, Eastern Division. 13 The deponent is Cathy Stewart. 14 Will counsel please identify 15 themselves. 16 MR. GOTTO: Gary Gotto and 17 Erika Keech of Keller Rohrbach, LLP, 18 for the plaintiffs. 19 MS. HERZFELD: Tricia Herzfeld 20 for the Tennessee plaintiffs. 21 MR. MCLAUGHLIN: Chris 22 McLaughlin from Jones Day on behalf of 23 Walmart. 24 MR. DAVISON: William Davison 25 and Kaitlin Bergin of Ropes & Gray on</p>	<p style="text-align: right;">Page 12</p> <p>1 to tell the truth, the whole truth and 2 nothing but the truth, deposes and says on 3 behalf of the Plaintiffs, as follows: 4 5 EXAMINATION 6 QUESTIONS BY MR. GOTTO: 7 Q. Good morning, Ms. Stewart. How 8 are you this morning? 9 A. I'm fine. Thank you. 10 Q. Okay. We have not met before 11 today, correct? 12 A. Correct. 13 Q. And as you heard when we made 14 appearances and we met briefly before we went 15 on the record, my name is Gary Gotto. I'm 16 with the law firm Keller Rohrbach. We're one 17 of the firms representing plaintiffs in the 18 national opiate litigation. 19 Just a few preliminary matters. 20 Have you ever given a deposition previously? 21 A. No, I have not. 22 Q. Okay. Have you ever testified 23 under oath in court? 24 A. No, I have not. 25 Q. Okay. So -- and I'm sure your</p>
<p style="text-align: right;">Page 11</p> <p>1 behalf of Mallinckrodt, LLC, SpecGx, 2 LLC, and on behalf of the witness. 3 VIDEOGRAPHER: The court 4 reporter will please swear in the 5 witness. 6 MR. GOTTO: Telephonic 7 appearances, too. 8 COURT REPORTER: Could everyone 9 on the phone please state their 10 appearance? 11 MS. SUNDERLAND: This is Sara 12 Sunderland with Covington & Burlington 13 for McKesson. 14 MS. PETERSEN: This is Miranda 15 Petersen with Williams & Connolly for 16 Cardinal Health. 17 MR. YINGLING: This is Patrick 18 Yingling with Reed Smith for 19 AmerisourceBergen. 20 MR. WATTS: This is Ryan Watts 21 with Arnold & Porter, Kay Scholer, on 22 behalf of Endo and Par entities. 23 24 CATHY STEWART, 25 of lawful age, having been first duly sworn</p>	<p style="text-align: right;">Page 13</p> <p>1 counsel has previously given you background 2 on this, but just to be sure we're all on the 3 same page, the court reporter will be taking 4 down a transcript of your testimony here 5 today. 6 A. Uh-huh. 7 Q. As you know, it's under oath. 8 You just took the oath, obviously. 9 A. Yeah. 10 Q. We're also taking video of the 11 proceedings. 12 If any of my questions are in 13 any way unclear to you, please let me know 14 and I'll do my best to clarify them. If you 15 answer a question without asking for 16 clarification, I'll assume the question was 17 clear to you. 18 Is that fair? 19 A. Yes. 20 Q. Okay. Please answer verbally, 21 yes or no, as compared to nods or shakes of 22 the head, et cetera, so that the court 23 reporter -- so that your response is 24 accurately reflected in the court reporter's 25 transcript.</p>

Page 14

1 Okay?

2 A. Okay.

3 Q. We'll take breaks periodically,

4 but anytime you need a break, please let me

5 know. If there's not a question pending, you

6 know, happy to take a break at any point that

7 you need it.

8 Okay?

9 A. Okay.

10 Q. Great.

11 Would you please state your

12 name and your business address, please?

13 A. My name is Catherine Stewart,

14 and I am now retired, so I have no business

15 address.

16 Q. Okay. When did you retire?

17 A. In 2013.

18 Q. Okay. What is your home

19 address?

20 [REDACTED]

21 [REDACTED]

22 Q. Okay. And when you retired --

23 what was your last employment before you

24 retired?

25 A. What was my job? My position?

Page 15

1 Q. Well, by whom were you employed

2 last --

3 A. Oh, okay.

4 Q. -- when you retired?

5 A. I was employed by Mallinckrodt

6 Pharmaceuticals.

7 Q. Great.

8 And when did you first become

9 employed by Mallinckrodt?

10 A. In 1995.

11 Q. Okay. Let's start with just a

12 brief bit of your background.

13 A. Uh-huh.

14 Q. Could you describe briefly your

15 post-high school education?

16 A. I attended college

17 intermittently. I worked for United Van

18 Lines for a period of time, and I had

19 17 years with the St. Louis City Police

20 Department and left there to go to

21 Mallinckrodt.

22 Q. Okay. And so with the police

23 department, generally describe what your

24 responsibilities were.

25 A. I was a stenographer, and I

Page 16

1 worked in internal affairs. And from there

2 we started to do automation, and I was in

3 charge of training the members of the

4 department in the use of an automatic --

5 automated police reporting system.

6 Q. Okay. And why did you leave

7 that position to join Mallinckrodt?

8 A. For better benefits.

9 Q. Okay. And when did you join

10 Mallinckrodt?

11 A. 1997.

12 Q. You indicated you attended

13 college intermittently.

14 Did you ever obtain a degree?

15 A. No, I did not.

16 Q. Okay. Do you have any sort of

17 professional certification or license?

18 A. I do. I'm certified in

19 inventory and production planning through an

20 organization called APICS, and I attended

21 St. Louis University's program for

22 certification in supply chain management.

23 Q. Okay. And apart from that

24 certification, do you hold any professional

25 licenses?

Page 17

1 A. No, I do not.

2 Q. Have you at any time?

3 A. No, I did not.

4 Q. Okay. When you -- can you

5 describe for me generally the positions that

6 you held at Mallinckrodt over the years?

7 A. Okay. My first position was

8 working for a gentleman that was working with

9 the federal government in remediating the

10 site from when Mallinckrodt refined the

11 uranium for the atomic bomb.

12 Then I moved into a position in

13 environmental where we disposed of the

14 hazardous waste and the waste streams that

15 came out of the production processes and took

16 them to our -- or had a company take them to

17 the appropriate disposal sites.

18 From there I moved into kind of

19 a transportation and warehousing side of the

20 business where I was responsible for

21 scheduling trucks into the plant for customer

22 shipments, for LTL, less than truckload, and

23 truckload shipments of non-narcotics.

24 From there I moved into a

25 planning function where I worked with

Page 18

1 marketing and the production facilities to
2 determine which products they needed to make,
3 when they needed to make it and how much they
4 needed to make.

5 From that position -- that was
6 at the plant level. Then I moved out to
7 corporate and was in kind of the same
8 position out there, but instead of focusing
9 just on the St. Louis plant, I focused on
10 multiple plants in the supply chain.

11 After I did that, I moved into
12 customer service and oversaw the customer
13 service representatives on the dosage side of
14 the business.

15 After that I moved into a
16 customer service management position on the
17 API side of the business and then back into
18 transportation and warehousing for a
19 third-party warehouse that we were using.

20 Q. Great. Thanks very much.

21 I'd like to focus on the time
22 periods and the positions you held that
23 pertain to any aspect of Mallinckrodt's
24 narcotics business.

25 A. Uh-huh.

Page 19

1 Q. I take it that would include
2 the period you were involved in customer
3 service.

4 A. Correct.

5 Q. Okay. Apart from that period
6 when you were involved in customer service,
7 for example, when you were involved in the
8 planning for marketing and production of
9 materials, did that involve the narcotics
10 business at all?

11 A. Some of it did, yes.

12 Q. Okay. Now, transport and
13 warehousing, I think you said that was
14 non-narcotics, right?

15 A. In the beginning, yes. When I
16 was in a later role and it was primarily with
17 customer service, we did some audits of our
18 transportation carriers just to make sure
19 that they were following our rules with
20 respect to transporting and transferring,
21 particularly FedEx.

22 Q. Okay. And that extended to
23 narcotics?

24 A. Yes.

25 Q. Okay. Is it fair -- I -- that

Page 20

1 to -- I assume that you were -- when you were
2 involved in either the hazardous waste
3 disposal or remediation aspects of the
4 business you described, that did not involve
5 narcotics?

6 A. Correct.

7 Q. Okay. And how about the last
8 area of responsibility you described where
9 you said you went back to transport and
10 warehousing; did that involve narcotics?

11 A. No, it did not.

12 Q. Okay. All right. So please
13 tell me what the time frames were -- let's
14 start with your -- the planning function that
15 you described. To the extent it had any --
16 any aspect of that function involved the
17 narcotics business, when did that -- when did
18 you first have those responsibilities?

19 A. This is -- my recollection of
20 dates is vague, but I would say it was
21 probably from 2006 to 2008.

22 Q. And tell me, during that time
23 period, to the extent your responsibilities
24 extended to the narcotics business, what were
25 your functions?

Page 21

1 A. Making sure that we had
2 sufficient inventory to cover customer orders
3 that came in. Making sure that we had
4 sufficient inventory to cover the customer
5 orders as well as the requirements needed to
6 manufacture our own dosage products at our
7 Hobart, New York, plant.

8 Q. And to whom did you report in
9 that -- in that position?

10 A. Michael Pheney, P-h-e-n-e-y.

11 Q. And who, if anyone, reported to
12 you when you were in that position?

13 A. I -- in the planning section, I
14 had no direct -- well, I had one direct
15 report: Matt Engelbart.

16 Q. And what was your title during
17 this period?

18 A. Planning manager.

19 Q. And to perform your duties as
20 planning manager, insofar as they pertained
21 to the narcotics business, was it necessary
22 for you to be familiar with any DEA
23 regulations or requirements?

24 A. Yes.

25 Q. And how did you become familiar

<p style="text-align: right;">Page 22</p> <p>1 with those regulations and requirements?</p> <p>2 A. We all had a copy of the Code</p> <p>3 of Federal Regulations, and it was incumbent</p> <p>4 on us to familiarize ourselves with those so</p> <p>5 that we were in compliance.</p> <p>6 We had a DEA compliance group</p> <p>7 that we discussed issues with or asked them</p> <p>8 to explain what the expectations were.</p> <p>9 Q. And can you recall the names of</p> <p>10 any of the individuals who were part of that</p> <p>11 DEA compliance group?</p> <p>12 A. Uh-huh. Yes.</p> <p>13 Q. Who --</p> <p>14 A. Karen Harper was the manager.</p> <p>15 Christie Kegg was one of her employees. Dave</p> <p>16 Hunter was one, and there was another woman</p> <p>17 named Robyn. I can't remember her last name.</p> <p>18 And she -- oh, she also had another</p> <p>19 gentleman. His name evades me right now. He</p> <p>20 was in charge of keeping track of our quota</p> <p>21 consumption and letting us know when we were</p> <p>22 bordering on situations where we were not</p> <p>23 going to have enough quota to meet a</p> <p>24 production schedule.</p> <p>25 Q. Okay. So prior to the time</p>	<p style="text-align: right;">Page 24</p> <p>1 that the court reporter can --</p> <p>2 THE WITNESS: Oh. Thank you.</p> <p>3 MR. GOTTO: It's a very natural</p> <p>4 tendency we all fall into, so...</p> <p>5 QUESTIONS BY MR. GOTTO:</p> <p>6 Q. So and I understand you had a</p> <p>7 copy of the Code of Federal Regulations. So</p> <p>8 when you first had responsibilities in</p> <p>9 connection with your planning function that</p> <p>10 required you to have some familiarity with</p> <p>11 DEA regulations and requirements, was there</p> <p>12 any sort of training program you went through</p> <p>13 that covered those requirements?</p> <p>14 A. Mallinckrodt did have training</p> <p>15 because it was required on an annual basis of</p> <p>16 all its employees. I don't recall specific</p> <p>17 training, but we had a myriad of training.</p> <p>18 There -- you know, that applied to -- you</p> <p>19 know, from disposable waste products to</p> <p>20 safety procedures and complying with the</p> <p>21 federal regulations and audits and inventory,</p> <p>22 you know, checking the -- so we can account</p> <p>23 for all of our consumption of the raw</p> <p>24 materials and that. So...</p> <p>25 Q. Okay. And obviously may have</p>
<p style="text-align: right;">Page 23</p> <p>1 that your job responsibilities involved --</p> <p>2 extended to any aspect of the narcotics</p> <p>3 business, did you have any personal</p> <p>4 familiarity or understanding of DEA</p> <p>5 regulations and requirements?</p> <p>6 A. Not to a great extent. Working</p> <p>7 with the police department, though, with RICO</p> <p>8 laws and seizing assets when persons are</p> <p>9 arrested with large amounts of drugs, I</p> <p>10 worked with a couple of people who actually</p> <p>11 retired from the police department and became</p> <p>12 DEA agents. So I did have some exposure to</p> <p>13 it.</p> <p>14 Q. Okay. But insofar as DEA</p> <p>15 regulations and requirements apply to</p> <p>16 Mallinckrodt's business --</p> <p>17 A. No.</p> <p>18 Q. -- prior to the time you were</p> <p>19 involved in the planning function, you didn't</p> <p>20 have any familiarity --</p> <p>21 A. No.</p> <p>22 Q. -- with those requirements,</p> <p>23 right?</p> <p>24 Okay. So --</p> <p>25 MR. DAVISON: Let him finish so</p>	<p style="text-align: right;">Page 25</p> <p>1 been many aspects of Mallinckrodt's business</p> <p>2 that implicated various federal</p> <p>3 regulations --</p> <p>4 A. Yes.</p> <p>5 Q. -- so I just want to focus here</p> <p>6 on DEA regulations for the moment.</p> <p>7 A. Okay.</p> <p>8 Q. Did I understand you correctly,</p> <p>9 you don't specifically remember training on</p> <p>10 DEA regulations as such?</p> <p>11 A. I remember having some</p> <p>12 training, but I can't be specific with what</p> <p>13 it was regarding.</p> <p>14 Q. Okay.</p> <p>15 A. But the aspect of the CFR, you</p> <p>16 know.</p> <p>17 Q. Okay. So is it fair to say you</p> <p>18 don't have a specific recollection of</p> <p>19 training with respect to DEA regulations or</p> <p>20 requirements as they pertain to</p> <p>21 Mallinckrodt's narcotics business?</p> <p>22 MR. DAVISON: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I did have some</p> <p>25 training; I just can't be specific as</p>

Page 26

1 to what it was in.
2 QUESTIONS BY MR. GOTTO:
3 Q. But you think it did extend to
4 DEA regulations pertaining to the narcotics
5 business?
6 A. Correct.
7 Q. Okay. Do you recall who
8 conducted that training?
9 A. No. No, I can't. I don't
10 recall.
11 Q. Okay. Was the training
12 conducted in a classroom setting?
13 A. Mallinckrodt had an auditorium,
14 so when the training was for the entire
15 plant, it was -- they scheduled multiple
16 sessions because it was a 24-hour operation,
17 so they could fit 200 employees in the room.
18 And so it was done that way in a big
19 auditorium.
20 Q. Okay. And do you recall if --
21 understanding you perhaps don't recall
22 specific individuals who conducted the
23 training, do you recall if they were
24 Mallinckrodt employees as compared to, say,
25 outside --

Page 27

1 A. Yes.
2 Q. -- personnel?
3 A. They were Mallinckrodt
4 employees.
5 Q. Okay. And again focusing on
6 training that pertained to DEA regulation or
7 requirements, do you recall the frequency of
8 any such training programs that you attended?
9 A. No.
10 Q. And do you recall if there were
11 any handouts or other materials you received
12 as part of those -- any of those training
13 programs?
14 A. I don't recall.
15 Q. Did you maintain personally any
16 sort of file or compilation of materials that
17 pertained to DEA regulations or requirements
18 for Mallinckrodt's narcotics business?
19 A. I don't recall.
20 Q. Now, I think you indicated that
21 there was a compliance group headed by
22 Ms. Harper, correct?
23 A. Yes.
24 Q. And did that group perform or
25 conduct any of the training sessions that you

Page 28

1 can recall?
2 A. I'm sure they did.
3 Q. Okay. Do you recall any of
4 those specifically?
5 A. No, but Mallinckrodt used
6 subject matter experts, so I'm sure it would
7 have been Karen's group that conducted the
8 training.
9 Q. Okay. So when -- when you were
10 performing the planning function that you
11 described, can you recall to any extent any
12 specific DEA regulations or requirements
13 that -- that you needed to be particularly
14 mindful of in order to do your job?
15 A. Yes.
16 MR. DAVISON: Objection to
17 form.
18 THE WITNESS: Yes.
19 QUESTIONS BY MR. GOTTO:
20 Q. And what can you recall?
21 A. Quota was probably the biggest
22 factor involved in the planning function
23 because the DEA allocated both procurement
24 quota to purchase the raw materials and
25 manufacturing quota to make the finished

Page 29

1 product. So we always had to be cognizant of
2 what quota we had remaining and whether or
3 not we could continue with the production run
4 legally, and when we were starting to get
5 towards the end of the quota, getting with
6 Karen's group to request additional quota
7 from the DEA.
8 Q. Okay. So -- and I think you
9 perhaps have alluded to the answer to this
10 question, but how did you become aware of
11 what the quota was at any given time?
12 A. The quota was always published
13 once a year by the DEA in the Federal
14 Register, so we knew what we had in each of
15 the molecules we manufactured. And one of
16 Karen's employees was responsible for
17 consuming -- you know, doing the adds and
18 subtracts as we made stuff, and he would let
19 us know we're getting -- you know, we can
20 probably make one more run but then we're
21 going to have to get quota before we can
22 manufacture anything else.
23 Q. Okay. And approximately how
24 many different molecules can you recall there
25 being quotas on during this period?

Page 30

1 A. Oh, lord. I'll say more than
2 10, less than 20.

3 Q. Do you recall any specific
4 examples of the molecules that there was
5 quota on?

6 A. Uh-huh. We did oxycodone. We
7 had quota on raw material, so opium, poppy
8 straw, and on most of our finished goods:
9 oxycodone, hydrocodone, fentanyl, morphine,
10 hydromorphone. Noscapine was a product, but
11 I don't recall if that was quota controlled.

12 And those were probably the big
13 ones. There were many others, but I don't
14 recall them.

15 Q. Okay. So again, focusing on
16 your planning function, tell me the specifics
17 of what your responsibilities were in that
18 function as it pertained to narcotics
19 business.

20 A. Once a month the marketing
21 group would put their sales forecast in the
22 computer to let me know what they anticipated
23 in sales going forward for the next
24 18 months.

25 I would evaluate that forecast

Page 31

1 for its validity because sometimes they were
2 a little optimistic with what they were going
3 to sell. So typically what I did was I took
4 their forecast and validated it against prior
5 forecasts compared to what their actual sales
6 numbers were in those periods, and then based
7 on that knowledge determined what I thought
8 would be an appropriate production run size.

9 Q. Did your planning
10 responsibilities extend to procurement?

11 A. Yes.

12 Q. And so how did you perform
13 those functions?

14 A. That was just a matter
15 of watching what the raw material inventories
16 were and entering a requisition into the
17 computer, and then there were purchasing
18 people that actually did the negotiations and
19 the purchase. I just let them know what I
20 was going to need and when I was going to
21 need it.

22 Q. Okay. And the planning
23 function that you've been describing, I think
24 you indicated you -- you started in that --
25 in that position in approximately 2006?

Page 32

1 A. I believe so.

2 Q. Do you recall the reason you
3 moved to that function from your prior
4 responsibilities at Mallinckrodt?

5 A. It was a promotion. It was for
6 advancement.

7 Q. Okay. And we've been using the
8 term "Mallinckrodt" describing your various
9 positions you held over the years.

10 Did you ever work for any
11 specific subsidiary of Mallinckrodt, or did
12 that ever change over time?

13 A. Mallinckrodt was purchased by
14 Tyco International at some point, so
15 Mallinckrodt became Tyco, and then after that
16 they became Covidien. And I can't recall if
17 they were still Covidien when I left or if
18 they were back to being Mallinckrodt, but
19 they've gone back and forth several times
20 over the years.

21 Q. Okay. But in terms of any
22 subsidiary of -- whether it's Covidien or
23 Mallinckrodt --

24 A. No.

25 Q. -- it was all the same to you?

Page 33

1 A. Yes.

2 Q. Okay. Well, let me circle back
3 to a few preliminary things I should have
4 touched on before we get into any of the
5 substantive things.

6 Could you describe for me --
7 and I don't want you to divulge any
8 communications you had with counsel, but
9 could you describe for me what you did to
10 prepare for today's deposition?

11 A. Reviewed some documents that
12 were attributed to me either via e-mail or --
13 that was about it, just e-mail and copies
14 of --

15 MR. DAVISON: I'm going to
16 instruct you not to answer on any
17 specific documents since they were
18 provided to you by counsel.

19 THE WITNESS: Okay.

20 MR. DAVISON: And that's
21 protected by work product.

22 THE WITNESS: All right.

23 QUESTIONS BY MR. GOTTO:

24 Q. Have you reviewed the
25 transcripts of any -- any testimony given by

Page 34

1 any other witness?
2 A. No.
3 Q. Have you spoken with any person
4 who has testified as a witness in this
5 litigation?
6 A. No.
7 Q. Apart from counsel, have you
8 spoken with anyone regarding any testimony
9 you anticipate giving?
10 A. No.
11 Q. With respect to the documents
12 that you reviewed, did any of them refresh
13 your recollection?
14 A. Yes.
15 Q. And in what regards can you
16 recall them refreshing your recollection?
17 MR. DAVISON: Again, I'm just
18 going to instruct you not to answer
19 with regards to any specific documents
20 that you reviewed.
21 THE WITNESS: Okay.
22 MR. DAVISON: If there's a
23 high-level information that you can
24 provide, you can do that --
25 THE WITNESS: Okay.

Page 35

1 MR. DAVISON: -- but I don't
2 want you to go into the specifics of
3 any documents or anything we
4 discussed.
5 THE WITNESS: Okay. There were
6 incidents that occurred over the
7 course of my career that I pretty much
8 had kind of forgotten about because
9 I've been away from it for so long.
10 So this, you know, was like, oh, yeah,
11 I remember that, you know, kind of a
12 thing.
13 QUESTIONS BY MR. GOTTO:
14 Q. Okay. And what were those
15 incidents?
16 A. We had a couple incidents where
17 customers were purchasing unusually large
18 quantities of a product, and my customer
19 service reps, being familiar with the
20 customers, knew that those were not normal
21 order quantities. So they brought it to my
22 attention, and we would investigate to try to
23 determine why the order was for such a large
24 quantity.
25 Q. Okay. Okay. And are you

Page 36

1 taking any medications that might affect your
2 ability to testify accurately today?
3 A. I don't believe so.
4 Q. Okay. Fair enough.
5 Okay. Let's go back to the
6 2006, 2008 period when you were involved in
7 the planning function you've been describing.
8 And I understand that you
9 reported to Mr. Pheney, and I understand that
10 you had interaction with the compliance group
11 that Ms. Harper held --
12 A. Uh-huh.
13 Q. -- headed up.
14 A. Yes.
15 Q. And I take it from your
16 testimony you also had interaction with the
17 marketing group in terms of their forecasts?
18 A. Correct.
19 Q. So who was in the marketing
20 group that you interacted with?
21 A. There were multiple people.
22 When I had the dosage side of the business,
23 there was John Adams, Victor Borelli. There
24 was a woman named Connie; I don't recall her
25 last name. And there were probably three or

Page 37

1 four other sales and marketing people.
2 Q. Okay. And you prefaced that
3 answer by saying when you had the dosage side
4 of the business.
5 A. Yes.
6 Q. Tell me what the dosage side of
7 the business is.
8 A. The dosage side of the business
9 is the pill form of the molecules.
10 Q. Okay. And what was the time
11 period when you had the dosage side of the
12 business?
13 A. '06 to '08? '09? I'm not
14 positive.
15 Q. Okay. And was this during the
16 period when you had the planning function
17 responsibilities?
18 A. No. This would have been --
19 that period would have been when I had dosage
20 customer service.
21 Q. Okay.
22 A. I believe.
23 Q. Okay. Let's focus first on the
24 time when you had the planning function.
25 A. Okay.

Page 38

1 Q. And in that function you
2 interacted with the marketing group?
3 A. Correct.
4 Q. So who, if anyone, can you
5 recall interacting with while you had --
6 while you were in the planning capacity?
7 A. Nick Litzsinger, John Adams,
8 Victor Borelli. I can't remember the other
9 people's names.
10 Q. Okay. Fair enough. Fair
11 enough.
12 And you may find over the
13 course of the day that something you're not
14 remembering at this moment may come to you
15 later on.
16 A. Uh-huh.
17 Q. If it does, feel free to let me
18 know --
19 A. Okay.
20 Q. -- later on.
21 So I just want to pin down with
22 as much specificity as we can the time
23 periods when you were in different roles at
24 Mallinckrodt.
25 A. Uh-huh.

Page 39

1 Q. And I think you testified early
2 on that you were in the planning -- you had
3 the planning function first at the plant
4 level and then at the corporate level,
5 correct?
6 A. Correct.
7 Q. So tell me, if you can, as best
8 you can, the specific time periods when you
9 had the planning function at the plant level
10 and then when you moved to the corporate
11 level.
12 A. I can't remember specific
13 dates.
14 Q. Okay. In terms of your moving
15 into the planning function at any level, is
16 2006 the approximate start time for that?
17 A. That's as good a guess as any.
18 Q. Okay. And when did you move
19 into the corp -- I'm sorry, the customer
20 service role?
21 A. I want to say maybe 2008.
22 Q. Okay.
23 A. I'm not positive.
24 Q. Okay. When you moved into the
25 customer service role, did your planning

Page 40

1 responsibilities shift to someone else?
2 A. Yes.
3 Q. And do you know who they
4 shifted to?
5 A. I don't recall.
6 Q. Okay. What was the reason for
7 you moving from the planning function to the
8 customer service function?
9 A. Because it was another aspect
10 of the supply chain management organization
11 that I hadn't had exposure to.
12 Q. Okay. Did you view that as a
13 promotion?
14 A. No, I viewed it as a lateral
15 move, but overall better for my career in the
16 long run.
17 Q. Okay. And the customer service
18 position, for how long did you hold that
19 position?
20 A. I'm going to say maybe three
21 years.
22 Q. So approximately 2008 to 2011?
23 A. I'm guessing, but, yes, I
24 suppose.
25 Q. And after 2011 -- well, after

Page 41

1 the customer service function, you moved back
2 to transport and warehouse function, correct?
3 A. Yes.
4 Q. And that's where you stayed
5 until your retirement?
6 A. Yes.
7 Q. Okay. And that function did
8 not involve the narcotics business, correct?
9 A. No, it did not.
10 Q. Okay. Can you give me an
11 approximation of your annual compensation
12 during the period 2006 to 2011?
13 A. It was about [REDACTED]
14 Q. And did that consist of a
15 salary and a bonus?
16 A. Yes.
17 Q. And approximately what percent
18 of the total was the bonus?
19 A. I don't recall. I want to say
20 [REDACTED].
21 Q. Okay. Was the bonus based on
22 any specific attainment of objectives or any
23 other sort of objective measure?
24 MR. DAVISON: Objection to
25 form.

Page 42

1 THE WITNESS: The -- yes, but
2 not for me specifically. It was for
3 the group. The group had objectives,
4 and as long as we obtained those, then
5 everyone in the group received the
6 flat bonus.
7 QUESTIONS BY MR. GOTTO:
8 Q. Okay. And is that true when
9 you were in the planning function, or is that
10 just for the customer service function?
11 A. No, Mallinckrodt did that for
12 every one of their employees.
13 Q. Okay. Was it a different group
14 when you were in the planning function versus
15 the customer service function?
16 A. There were different
17 objectives.
18 Q. Okay. Can you describe
19 generally when you were in the planning
20 function what those objectives were?
21 A. Obviously not running out of
22 inventory. Having the inventory so we could
23 ship the customer orders on time. Those were
24 usually the prime objectives.
25 Q. How about when you were in the

Page 43

1 customer service role?
2 A. They would have been about the
3 same. Shipping within -- on the dosage side
4 of the business, we tried to ship within
5 24 hours of order receipt.
6 Q. So let's focus now on your
7 period of time in customer service, and
8 describe for me generally what your
9 responsibilities were in that function.
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: I supervised six
13 customer service reps that were
14 responsible for all of the customers
15 in the United States and made sure we
16 complied with the regulations in the
17 sense that when the order was placed,
18 it didn't ship until we received a
19 properly executed 222 form. And that
20 was kind of the big thing.
21 Obviously there were metrics
22 for performance standards for some of
23 the girls, but that was the big
24 objective.
25

Page 44

1 QUESTIONS BY MR. GOTTO:
2 Q. Okay. And the -- were your
3 responsibilities limited to the dosage side
4 of the business?
5 A. At that time, yes.
6 Q. Were there times when you had
7 customer service responsibilities that
8 extended beyond the dosage side of the
9 business?
10 A. I moved into customer service
11 for the API side of the business later on.
12 Q. And approximately when?
13 A. I'm going to say it was two
14 years after I started in dosage they moved me
15 to API.
16 Q. So approximately 2010?
17 A. Yeah.
18 Q. And tell me what you mean by
19 API.
20 A. Those are the bulk narcotics,
21 so the API would be drums of pure oxycodone,
22 not mixed with APAP or Tylenol or anything,
23 that would be shipped to other manufacturers
24 so that they could make their own dosage
25 products.

Page 45

1 Q. Okay. Is that the active
2 pharmaceutical ingredient?
3 A. Yes.
4 Q. When you moved into API, did
5 you continue to have responsibility for
6 dosage?
7 A. No.
8 Q. Okay. So those are -- are
9 those two sort of mutually exclusive
10 categories?
11 A. Yes.
12 Q. Okay. So it sounds like you
13 were -- you had customer service
14 responsibility for dosage approximately 2008
15 to 2010, and then for API approximately 2010,
16 2011?
17 A. Correct.
18 Q. Okay. All right. And when you
19 moved from dosage to API customer service
20 responsibility, did you view that as a
21 promotion?
22 A. No. Once again, a lateral
23 move.
24 Q. Okay. And what was the reason
25 for making that move?

Page 46

1 A. I think they were reorganizing
 2 the logistics organization under a new vice
 3 president, so they were shifting people
 4 around, bringing some new people up through
 5 the ranks into other positions.
 6 Q. Okay. When you moved into the
 7 customer service position in approximately
 8 2008, who was your predecessor in that
 9 position with respect to dosage?
 10 A. Sean Welch, W-e-l-c-h.
 11 Q. Is that a man or a woman?
 12 A. He's a man.
 13 Q. Okay. And so did Mr. Welch --
 14 do you know why he moved out of that
 15 position?
 16 MR. DAVISON: Objection to
 17 form.
 18 THE WITNESS: He left the
 19 company to accept another position.
 20 QUESTIONS BY MR. GOTTO:
 21 Q. Okay. When you moved into the
 22 customer service position, was there any
 23 training you went through to prepare yourself
 24 for those responsibilities?
 25 A. Not prior to the move but

Page 47

1 during the move customer service reps helped
 2 get me up to speed, and then Karen and I
 3 talked a great deal about what the
 4 requirements were. Again, I had a copy of
 5 the CFR to refer to, knew what some of the
 6 expectations were with regard to clearing a
 7 222 form within 24 hours of shipment and
 8 things like that.
 9 Q. Okay. And so no formal
 10 classroom training; more on-the-job training
 11 type thing?
 12 A. No, more of on-the-job
 13 training, yes.
 14 Q. Okay. And did you talk to
 15 Mr. Welch at all in the transition to get any
 16 guidance from him?
 17 A. Yes.
 18 Q. What can you recall in that
 19 regard?
 20 A. Sean and I were friends, so
 21 when I had a question about something, I
 22 would call him and try to bounce something
 23 off of him, ask his opinion.
 24 Q. Okay. Were there aspects of
 25 DEA regulation or requirements that you

Page 48

1 needed to be familiar with to perform your
 2 customer service responsibilities that were
 3 different from DEA requirements and
 4 regulation that you needed to be familiar
 5 with to perform your planning function?
 6 MR. DAVISON: Objection. Form.
 7 THE WITNESS: Yes.
 8 QUESTIONS BY MR. GOTTO:
 9 Q. And what are the differences
 10 you can recall?
 11 A. On the customer service side of
 12 the business, your focus was on 222 forms,
 13 making sure that the customers had them
 14 before we could -- that we were in possession
 15 of them before we could ship any product to
 16 the customer.
 17 On the planning side of the
 18 business, the focus was more on quota. Can
 19 we legally procure the raw materials,
 20 manufacture the product and have it ready for
 21 distribution.
 22 Q. Okay. And the quota was
 23 Mallinckrodt's quota, right?
 24 A. Yes.
 25 Q. Okay. And so tell me what a

Page 49

1 222 form is.
 2 A. A 222 form is issued by the DEA
 3 to each registrant who purchases dosage or
 4 API product. They fill out specifics with
 5 regard to what product they want to purchase
 6 and the quantity they want to purchase.
 7 Once we receive that form, the
 8 222 form number was entered into the system
 9 to release the order. So that told everybody
 10 it's legal, we have the 222 form, we can ship
 11 this.
 12 Then after the shipment is
 13 executed, you go back to the form and you
 14 fill out how much was shipped and when it was
 15 shipped, and that form goes back to the DEA.
 16 Q. Okay. So did a customer
 17 provide a 222 form for each order?
 18 A. Yes.
 19 Q. Okay. And --
 20 A. There were -- you could order
 21 multiple products on each 222 form.
 22 Q. Okay. Give me an example of
 23 how that would work.
 24 A. There were multiple lines on
 25 the form, maybe eight lines, so I could order

Page 50

1 oxycodone on one line, methadone on another
 2 line, hydromorphone on another line. So once
 3 each form tied back to an order -- and they
 4 had to be a 100 percent match to be legal.
 5 Q. So the 222 form, just trying to
 6 understand, would it -- would it be with
 7 reference to a specific dosage product or
 8 would it be with reference to some quantity
 9 of the API?
 10 A. They're used for purchases of
 11 both dosage and API. When you order dosage
 12 products on a 222 form, you order it in
 13 bottles or cases.
 14 When you order API on a 222
 15 form, it's ordered in grams or kilos.
 16 Q. Okay. And so, for example --
 17 let's talk first about a bulk order and how a
 18 222 form would work.
 19 A. Uh-huh.
 20 Q. Would the 222 form be specific
 21 to a particular API and identify a quantity
 22 of that that could be ordered?
 23 A. Each line would be a specific
 24 API and quantity, but you could order
 25 multiple molecules, like 2, 8, or however

Page 51

1 many lines were on it. So you could order
 2 morphine, oxycodone, you know, different
 3 products on each 222 form.
 4 Q. Okay. And as long as the
 5 amount ordered for each of those products was
 6 not greater than the amount set forth on the
 7 222 form, that order could be fulfilled?
 8 A. Yes.
 9 Q. Okay. Now, let's talk about a
 10 222 form in a dosage order.
 11 A. Okay.
 12 Q. What format would that take?
 13 Would it, for example, identify specific --
 14 say a 15-milligram tablet or 100-tablet
 15 bottle of a 15-milligram product?
 16 A. Correct. The order quantities
 17 would typically be 12 cases of oxycodone
 18 5/325. So a case might have been six
 19 100-count bottles of oxycodone, where you've
 20 got 5 milligrams of oxycodone and
 21 325 milligrams of acetaminophen. So those
 22 are ordered in cases, typically.
 23 Sometimes smaller operations
 24 like methadone clinics would order bottles of
 25 methadone rather than cases because they

Page 52

1 didn't keep inventory in hand, so their
 2 orders went almost every day, so...
 3 Q. Okay. And typically -- well, I
 4 shouldn't say -- strike that.
 5 Were there occasions when
 6 the -- when the -- let's focus on dosage here
 7 for a moment -- when the 222 form would
 8 extend to a greater quantity of product than
 9 was being ordered?
 10 MR. DAVISON: Objection. Form.
 11 THE WITNESS: Could you ask
 12 again?
 13 QUESTIONS BY MR. GOTTO:
 14 Q. Sure.
 15 Were there occasions when the
 16 222 form extended to a greater quantity of
 17 product than the customer was placing an
 18 order for?
 19 MR. DAVISON: Same objection.
 20 THE WITNESS: I don't believe
 21 so.
 22 QUESTIONS BY MR. GOTTO:
 23 Q. Okay. So best you can recall,
 24 the 222 form would apply to exactly the
 25 number of product that the customer was

Page 53

1 ordering?
 2 A. That were going to -- yes.
 3 Yes. The only time there was a discrepancy
 4 is if a customer ordered ten cases of
 5 something, and when the material handlers
 6 pulled the product for shipment, one of the
 7 boxes may have been damaged, so it would not
 8 have been safe to put in transport because we
 9 would have had bottles flying around. So
 10 they may have shipped the line short, but you
 11 could never ship more than what the customer
 12 requested.
 13 Q. Okay. So again focusing on
 14 dosage, did customers place orders on a
 15 monthly basis?
 16 A. It depended. Some big
 17 customers like Walmart, we typically had a
 18 truckload that went to their Bentonville
 19 facility once a week. Smaller ones, you
 20 know, small pharmacies, maybe once every two
 21 weeks. Some places once a month. It just
 22 depended on were they a distributor, a
 23 pharmacy, a -- you know, is it a Walgreens
 24 versus Kathy's Pharmacy, you know, or a
 25 methadone clinic.

Page 54

1 So they -- the same customers
 2 typically ordered in the same cycle. You
 3 know, their orders were cyclical, and it was
 4 either monthly or weekly or whatever. But
 5 there was no common denominator across all of
 6 the customers for how frequently they
 7 ordered.

8 Q. Okay. And is it the case that
 9 each order needed to be accompanied with --
 10 by a 222 form?

11 A. Yes.

12 Q. And the 222 form was issued by
 13 the DEA; is that correct?

14 A. The 222 forms are issued by the
 15 DEA to the customer. When the customer
 16 places an order with us, they fill out the
 17 222 form to match the line items that they're
 18 ordering. They would FedEx them overnight to
 19 us.

20 Once we were in possession of
 21 that, we'd validate it against what was in
 22 the system, enter the 222 form number on the
 23 order as confirmation, and then the order was
 24 allowed to drop at the Hobart facility so it
 25 could ship.

Page 55

1 Q. Okay. And so let's say a
 2 customer who was ordering monthly, on a
 3 monthly cycle.

4 A. Uh-huh.

5 Q. Would that customer have gone
 6 to the DEA then on a monthly basis to get a
 7 222 form to support its order that it was
 8 going to place?

9 MR. DAVISON: Objection to the
 10 form.

11 THE WITNESS: I don't think
 12 that was the case. I think they
 13 issued multiple 222 forms that were --
 14 the registrant's information was
 15 preprinted at the top, but the bottom
 16 of the form was blank, so they could
 17 use them on an as-needed basis.

18 They did not give them like a
 19 year's worth, but, you know, you might
 20 get 20 of them at a time, and then
 21 when your inventory started to shrink,
 22 you'd request more.

23 QUESTIONS BY MR. GOTTO:

24 Q. Okay. So the 222 form that
 25 Mallinckrodt received from its customer --

Page 56

1 let's take the example of a customer who
 2 got -- let's say got ten 222 forms from the
 3 DEA at a given time.

4 Would that customer then take
 5 one of those 222 forms and fill it out to
 6 reflect the order it was placing with
 7 Mallinckrodt at a given time?

8 A. Usually they would call us and
 9 place the order without the quantity. They
 10 would tell us what they'd want, but there
 11 were many cases where inventory was tight, so
 12 they may have wanted 30 cases but we might
 13 have only had 20 in inventory. So they
 14 didn't fill out the quantity on the 222 form
 15 until after they confirmed that we were able
 16 to send them the quantity.

17 Q. Okay. But once they confirmed
 18 that you did have the quantity available to
 19 ship --

20 A. Yes.

21 Q. -- the customer would then
 22 complete the 222 form and provide it to you?

23 A. Correct.

24 Q. Okay. Did that same general
 25 procedure apply in the bulk side of the

Page 57

1 business?

2 A. Yes, it did.

3 Q. So Mr. Welch preceded you in
 4 the customer service role for dosage?

5 A. Correct.

6 Q. When you transitioned over to
 7 bulk in approximately 2010, do you know who
 8 succeeded you in the dosage side customer
 9 service role?

10 A. I believe it was Bonita
 11 Rohling, R-o-h-l-i-n-g.

12 Q. And had you worked with
 13 Ms. Rohling?

14 A. Uh-huh.

15 Q. Was she one of the people who
 16 reported to you?

17 A. No, she was not.

18 Q. Okay. What had been her role,
 19 if you know, prior to taking over the
 20 customer service for dosage?

21 A. She was --

22 MR. DAVISON: Let him finish.

23 THE WITNESS: She was involved
 24 in a system conversion. She worked in
 25 the same organization I did, in the

Page 58

1 logistics organization, but we were
2 converting our computer systems to a
3 JDE system, and she was involved with
4 teaching all of the plants how to use
5 it and how the, you know, inventory
6 worked and how to look at it and know
7 what we had and what we needed.
8 **QUESTIONS BY MR. GOTTO:**
9 Q. Okay. And when the transition
10 occurred from you to Ms. Rohling, did you
11 take any steps to train her or prepare her
12 for the job?
13 A. Yes, we reviewed many things,
14 and I was right there as well, so she
15 could -- just a few cubes over, so she could
16 always come and consult me about something.
17 Q. Okay. When you moved over to
18 the bulk side of the business in 2010,
19 approximately 2010, who was your predecessor
20 in that position?
21 A. Jim Rausch.
22 Q. Okay. And when you
23 transitioned out of that position in
24 approximately 2011, who succeeded you in that
25 position?

Page 59

1 A. You know what? I misspoke.
2 Bonita did not succeed me in dosage. She --
3 it was API --
4 Q. Okay.
5 A. -- that Bonita -- I can't
6 remember who replaced me in dosage.
7 Q. Okay. So just so we have the
8 sequence in dosage, it had been Mr. Welch.
9 A. Right.
10 Q. You succeeded him. You don't
11 recall who succeeded you?
12 A. No.
13 Q. Okay. And in bulk, it had been
14 Mr. Rausch. You succeeded him, and then
15 Ms. Rohling succeeded you?
16 A. Yes.
17 Q. Okay. Great.
18 When you moved into bulk and
19 took over for Mr. Rausch, do you know what
20 position he moved into?
21 A. He moved into another customer
22 service capacity for imaging and respiratory
23 products, if memory serves me correctly.
24 Q. Okay. Had you worked with him
25 in any -- prior to moving into the bulk

Page 60

1 customer service position, had you worked
2 with Mr. Rausch?
3 A. We interfaced when I was in
4 planning.
5 Q. And what --
6 A. And shipping.
7 Q. Okay. And what role did he
8 play at that time when you interfaced with
9 him?
10 A. We would get orders for
11 non-narcotic products, and if the system was
12 incorrect in stating how much we had in
13 inventory and the material handlers would
14 call that to my attention, and then I would
15 get hold of Jim so they could notify the
16 customer that even though they placed an
17 order for ten and we thought we had it, we
18 did not.
19 Q. Okay. But was he in the
20 customer service role at that point?
21 A. Yes.
22 Q. And were his responsibilities
23 for the bulk side of the business at that
24 time?
25 A. Yes.

Page 61

1 **MR. DAVISON:** We've been going
2 about an hour. Is now a good time to
3 take a break?
4 **MR. GOTTO:** You bet. Sure.
5 **VIDEOGRAPHER:** We're going off
6 the record at 10:02 a.m.
7 (Off the record at 10:02 a.m.)
8 **VIDEOGRAPHER:** We are back on
9 the record at 10:17 a.m.
10 **QUESTIONS BY MR. GOTTO:**
11 Q. Ms. Stewart, before the break
12 you indicated that Ms. Harper headed up the
13 DEA compliance group, correct?
14 A. Correct.
15 Q. And was that during the entire
16 period that you had the customer service
17 function?
18 A. Correct.
19 Q. You interacted with Ms. Harper
20 fairly regularly; is that fair?
21 A. Yes.
22 Q. Okay. Did you have any views
23 as to her effectiveness in functioning as the
24 head of the DEA compliance group?
25 A. Yes, I thought she was very

Page 62

1 good at what she did.
2 Q. Did she appear to be
3 knowledgeable with respect to applicable DEA
4 requirements?
5 A. Yes.
6 Q. And was she responsive to
7 questions you would pose to her?
8 A. Yes, she was.
9 Q. I think you also indicated that
10 you interacted with Mr. Adams from time to
11 time on behalf of -- where he was acting on
12 behalf of the marketing group or as part of
13 the marketing group, right?
14 MR. DAVISON: Objection. Form.
15 THE WITNESS: Correct.
16 QUESTIONS BY MR. GOTTO:
17 Q. Do you recall what specific
18 role he had in the marketing group?
19 A. I believe he was supervisor for
20 some of the sales reps.
21 Q. Okay. And did you form any
22 view with respect to Mr. Adams' effectiveness
23 in performing his job?
24 A. No.
25 Q. Did anyone ever come to you

Page 63

1 with any -- and express any criticisms or
2 concerns with respect to Mr. Adams?
3 A. No.
4 Q. Now, you mentioned you
5 succeeded Mr. Rausch with respect to the bulk
6 customer service business in approximately
7 2010, correct?
8 A. I'm not clear on the dates,
9 but, yes, uh-huh.
10 Q. At some point?
11 A. At some point, yes.
12 Q. And Mr. Rausch is someone that
13 you had interacted with periodically,
14 correct?
15 A. Yes.
16 Q. Did you have occasion to form
17 any opinion with respect to Mr. Rausch's
18 effectiveness in performing his job at
19 Mallinckrodt?
20 A. Jim was very competent. He had
21 done it for many years.
22 Q. Okay. Was he -- did he appear
23 to you to be knowledgeable with respect to
24 applicable DEA requirements and regulations?
25 MR. DAVISON: Objection. Form.

Page 64

1 THE WITNESS: I don't know how
2 knowledgeable he was in them.
3 QUESTIONS BY MR. GOTTO:
4 Q. Okay. Was he responsive to any
5 questions you might pose to him from time to
6 time?
7 A. Yes.
8 Q. You also indicated that you
9 interacted with Mr. Borelli from time to time
10 on behalf of the marketing group, correct?
11 A. Correct.
12 Q. And do you recall what specific
13 function Mr. Borelli had?
14 A. He was a salesman for
15 Mallinckrodt.
16 Q. Okay. Did you have occasion to
17 form any opinion with respect to his
18 effectiveness in performing his job at
19 Mallinckrodt?
20 A. No.
21 Q. Did anyone ever come to you and
22 express any concern or criticism of any
23 aspect of Mr. Borelli's job performance?
24 A. Yes.
25 Q. What can you recall in that

Page 65

1 regard?
2 A. Victor would -- because of the
3 location of the Hobart plant, it was pretty
4 remote, so we tried to get orders to them by
5 a cutoff time to give the material handlers
6 sufficient time to pick and pack the order
7 before the trucks got there to pick them up.
8 Victor would always come in at
9 the very tail end of the day and want us to
10 authorize overtime and -- to get one more
11 shipment out the door, you know, for one of
12 his customers. And so it was -- sometimes he
13 was a pain, but, you know, that kind of a
14 thing.
15 Q. Okay. And so you can recall
16 more than one occasion that someone expressed
17 that sort of concern to you about
18 Mr. Borelli?
19 A. Yes.
20 Q. Do you recall anyone expressing
21 any concern to you with respect to
22 Mr. Borelli's communications with customers?
23 A. No.
24 Q. Okay. I'd like to circle back
25 to the period when -- when you had the

Page 66

1 customer service responsibility for the
 2 dosage side of the business.
 3 A. Uh-huh.
 4 Q. And if I understood your
 5 testimony correctly before the break, one of
 6 your responsibilities during that period was
 7 to verify that each order was supported by a
 8 proper 222 form, correct?
 9 A. Correct.
 10 Q. And is that a determination
 11 that you personally made?
 12 A. No. The customer service reps
 13 knew that an order could not be released
 14 without a 222 form, and the system -- the
 15 order entry system required the entry of the
 16 222 form number in the actual order before it
 17 would drop for shipping.
 18 Q. And so who -- physically who
 19 was the person who input that into
 20 Mallinckrodt's system, that 222 order number?
 21 A. Each customer service rep
 22 handles their 222 forms for their customer
 23 base.
 24 Q. Okay. And those are -- when
 25 you say "customer service reps," those are

Page 67

1 the six people --
 2 A. Yes.
 3 Q. -- you supervised?
 4 A. Correct.
 5 Q. Okay. So in terms of actually
 6 physically reviewing the 222 form and
 7 entering it into the system, that's something
 8 that one of your six supervised CSRs did,
 9 correct?
 10 A. Each of them did it, yes.
 11 Q. Okay. And was there any
 12 process in place to review their work in that
 13 regard?
 14 A. Yes. After the orders were
 15 ship confirmed by the plant, the next day we
 16 would pull all of the 222 forms and
 17 confirm -- validate against the system what
 18 was ordered, what was shipped, and do those
 19 numbers, quantities and product codes match
 20 what's on the 222 form.
 21 Q. And who would perform that
 22 function?
 23 A. Mostly the customer service
 24 reps. There were a lot of times I did it
 25 just as checks and balances, and then

Page 68

1 ultimately those forms went back to the DEA.
 2 Q. Okay. When it was the customer
 3 service rep who did this next-day validation,
 4 was it the same person who input the order
 5 into the system in the first place?
 6 A. Not always.
 7 Q. Okay. It could be, but not
 8 always?
 9 A. Right.
 10 Q. Okay. And again focusing on
 11 the period during which you had the customer
 12 service function for the dosage side of the
 13 business, apart from confirming that there
 14 was a proper 222 form for an order, was there
 15 any other review that the customer service
 16 department performed of any order to confirm
 17 compliance with any DEA regulation or
 18 requirement?
 19 A. No.
 20 Q. Now, during the period when you
 21 had the customer service function for the
 22 bulk side of the business, for the API -- are
 23 those synonymous, bulk and API?
 24 A. Yes.
 25 Q. Okay.

Page 69

1 A. Yes.
 2 Q. Okay. So during that period
 3 when you had the bulk side of the business,
 4 again, part of the function was to confirm
 5 that there was a proper 222 form for every
 6 order, correct?
 7 A. Correct.
 8 Q. And was it a similar process in
 9 terms of who actually input the 222 form into
 10 the system?
 11 A. Correct.
 12 Q. And was it the same group of
 13 customer service reps who you were
 14 supervising when you moved over to the bulk
 15 side?
 16 A. No.
 17 Q. Okay. And do you recall
 18 approximately how many customer service reps
 19 you supervised when you were on the bulk
 20 side?
 21 A. Six or seven.
 22 Q. Okay. But they were different
 23 people than had been in dosage?
 24 A. Yes.
 25 Q. Okay. But the -- but it was a

Page 70

1 similar process in terms of one of them would
 2 input the 222 form when the order was put in
 3 the system?
 4 A. Correct. Or -- and on the bulk
 5 side there were international orders, so
 6 those used a different form, but it was the
 7 equivalent of an international 222.
 8 Q. Okay. And the international
 9 222, is that a DEA form?
 10 A. I believe it was.
 11 Q. So were there no international
 12 orders on the dosage side of the business?
 13 A. Correct.
 14 Q. Okay. Again, focusing on the
 15 bulk side, was there the -- a similar
 16 next-day validation process similar to the
 17 one you described for the dosage business?
 18 A. No.
 19 Q. Was there any sort of
 20 validation process?
 21 A. Yes.
 22 Q. What was it?
 23 A. Once the order was ship
 24 confirmed, each of the bulk orders was a
 25 custom package based on the quota that the

Page 71

1 customer had. So it wasn't a matter of
 2 picking up a 10-kilo drum and putting a label
 3 on it. Typically they had to weigh each one.
 4 So customers would order
 5 7.495 kilos, so we would measure out
 6 7.495 kilos, and that took time. So their
 7 orders might take a week or two to get
 8 packaged and shipped. Once it was shipped,
 9 then we did the validation on the 222 form.
 10 Q. Okay. So for a bulk customer,
 11 was there a quota review separate from the
 12 222 form review?
 13 A. No. They submitted the 222
 14 form. We were under the impression that they
 15 had quota to make the purchase.
 16 Q. Okay. So you didn't engage in
 17 any other -- well, strike that.
 18 For a bulk purchaser -- strike
 19 that. Let me step back.
 20 You had indicated earlier
 21 Mallinckrodt, as a manufacturer, had a DEA
 22 quota, both with respect to procurement --
 23 A. Yes.
 24 Q. -- of raw material and
 25 production of finished product, correct?

Page 72

1 A. Correct.
 2 Q. Okay. And so would
 3 Mallinckrodt's bulk customers have similarly
 4 had DEA quota with respect to their
 5 procurement and production?
 6 A. Correct.
 7 Q. Okay. And so when Mallinckrodt
 8 was filling an order, a bulk order, for a
 9 customer, apart from the 222 form review
 10 process we've discussed, was there any other
 11 process in place to verify that the order was
 12 within that customer's quota?
 13 A. No, we had no way.
 14 Q. Okay. Did Mallinckrodt get any
 15 sort of confirmation or representation from
 16 the customer that the order was within that
 17 customer's DEA quota?
 18 MR. DAVISON: Object to the
 19 form.
 20 THE WITNESS: It was verbal,
 21 and by virtue of the 222 form we made
 22 the assumption that they did, knowing
 23 that the 222 form was going back to
 24 the DEA for audit. So if they
 25 attempted to procure more than they

Page 73

1 had quota, then the DEA would follow
 2 up.
 3 QUESTIONS BY MR. GOTTO:
 4 Q. Looking back at -- looking at
 5 Mallinckrodt as a procurer of raw material
 6 for its own manufacturing, were you ever
 7 involved in -- did you ever have a job at
 8 Mallinckrodt that involved responsibility
 9 that touched on that process?
 10 A. Other than entering
 11 requisitions to let the purchasing agents
 12 know that we were going to need this much
 13 opium by this date.
 14 Q. Okay. So do you have any
 15 familiarity with what sort of information or
 16 documentation Mallinckrodt provided to its
 17 sources when it procured raw material?
 18 A. I do not know.
 19 Q. Okay. Are you familiar with
 20 the term "diversion" as it applies to
 21 narcotics?
 22 A. I am.
 23 Q. And what do you understand that
 24 term to mean?
 25 A. It's when product is absconded

Page 74

1 or does not reach the intended recipient and
 2 ends up on the streets.
 3 Q. Okay. And let's focus first on
 4 the dosage side of Mallinckrodt's business.
 5 A. Okay.
 6 Q. Can you describe for me
 7 generally who the customers of Mallinckrodt
 8 were for the dosage products?
 9 A. Dosage?
 10 We had large pharmaceutical
 11 chains. We had Walmart, Walgreens. We had
 12 distributors like McKesson. Oh, I can't
 13 think of all of them. We had methadone
 14 clinics. But I would say mostly
 15 distributors, pharmaceutical chains and
 16 methadone clinics were the primary customers.
 17 Q. Okay. Were there any
 18 single-location pharmacies that were
 19 customer -- direct customers of Mallinckrodt
 20 for dosage product?
 21 A. There may have been some single
 22 location, but they were distributors, not --
 23 Q. Retail?
 24 A. Yeah, thank you.
 25 Q. All right. And when you use

Page 75

1 the term "distributor," what do you mean by
 2 that?
 3 A. I mean in the case of Walmart
 4 we would ship to their Bentonville, Arkansas,
 5 facility because that's where they secured
 6 all their narcotics, and then from that
 7 facility they distributed to their pharmacies
 8 around the country.
 9 Q. Okay. Did you have an
 10 understanding as to whether Walmart sold to
 11 other pharmacies, or did they buy from
 12 Mallinckrodt for the purpose of distributing
 13 to their own pharmacies and then sell at
 14 retail?
 15 MR. MCLAUGHLIN: Objection to
 16 form and no foundation.
 17 MR. DAVISON: Objection to
 18 form.
 19 THE WITNESS: My impression,
 20 that it was for their own use, but I
 21 have no reason to -- no way to verify
 22 that.
 23 QUESTIONS BY MR. GOTTO:
 24 Q. Okay. How about -- let's say
 25 McKesson. McKesson was a distributor,

Page 76

1 correct?
 2 A. Uh-huh.
 3 Q. Did you have an understanding
 4 of McKesson's distribution business as it
 5 pertained to narcotics it was acquiring from
 6 Mallinckrodt?
 7 MR. DAVISON: Objection to
 8 form.
 9 THE WITNESS: No.
 10 QUESTIONS BY MR. GOTTO:
 11 Q. When I asked you about
 12 diversion a little earlier, you indicated
 13 your understanding was diversion was some --
 14 was something that would result in the
 15 narcotic going other than to its intended
 16 customer from Mallinckrodt's standpoint,
 17 correct?
 18 A. Correct.
 19 Q. And would that extend to
 20 diversion at a step removed from
 21 Mallinckrodt's chain -- place in the
 22 distribution chain?
 23 So, for example, if McKesson
 24 were to acquire from Mallinckrodt, and then
 25 if McKesson's customer permitted the product

Page 77

1 to fall into the wrong hands, would you
 2 include that in your definition of diversion?
 3 MR. DAVISON: Objection to the
 4 form.
 5 THE WITNESS: I would, although
 6 controlling -- trying to control their
 7 diversion would not be Mallinckrodt's
 8 responsibility.
 9 QUESTIONS BY MR. GOTTO:
 10 Q. So did you understand during
 11 the time you had customer service
 12 responsibility at Mallinckrodt or during the
 13 time you had planning responsibility that
 14 extended to the narcotic products that
 15 Mallinckrodt had any responsibility to
 16 prevent diversion?
 17 MR. DAVISON: Objection. Form.
 18 THE WITNESS: Yes.
 19 QUESTIONS BY MR. GOTTO:
 20 Q. And what did you understand
 21 that responsibility to be?
 22 A. That we had to take steps to do
 23 everything in -- reasonably within our power
 24 to prevent diversion from the time it left
 25 our facility to the time the customer signed

Page 78

1 for receipt of the product.
2 Q. And what was the source of your
3 understanding of Mallinckrodt's
4 responsibility in that regard?
5 A. The DEA regulations.
6 Q. And was that based on your own
7 review of DEA regulations or was it based on
8 something you learned in either a training
9 program or otherwise from someone else at
10 Mallinckrodt?
11 A. Both.
12 Q. Okay. To the extent it's
13 something that you learned in a training
14 program or from someone else at Mallinckrodt,
15 do you recall the source of that information?
16 A. Most of those conversations
17 took place with Karen Harper.
18 Q. And was it your understanding
19 that as long as the product was received by
20 Mallinckrodt's intended customer, that
21 Mallinckrodt had no further responsibility
22 with respect to diversion of that product?
23 MR. DAVISON: Objection to
24 form.
25 THE WITNESS: Correct.

Page 79

1 QUESTIONS BY MR. GOTTO:
2 Q. And what was the basis for that
3 understanding?
4 MR. DAVISON: Same objection.
5 THE WITNESS: The Code of
6 Federal Regulations. That was my
7 interpretation of the regulation.
8 DEA is very vague in what they
9 suggest that you do, so it's open to
10 interpretation. And our
11 interpretation was once we received a
12 proof of delivery from a customer that
13 they physically had it in their
14 possession, then our liability ended.
15 QUESTIONS BY MR. GOTTO:
16 Q. Okay. And in terms of that
17 understanding, is that something that was
18 communicated to you by anyone else at
19 Mallinckrodt?
20 A. Probably Karen and I had
21 discussions in that regard -- regard. We had
22 discussions with our carriers in that regard
23 as well.
24 Q. When you say "carriers," you
25 mean Federal Express --

Page 80

1 A. Our trucking companies, yes.
2 Q. Okay. Was the prevention of
3 diversion something that you viewed as an
4 important part of your job responsibility?
5 MR. DAVISON: Objection to
6 form.
7 THE WITNESS: Absolutely.
8 QUESTIONS BY MR. GOTTO:
9 Q. And why did you view it as
10 important?
11 MR. DAVISON: Same objection.
12 THE WITNESS: Because if we
13 didn't exercise caution and abide by
14 the regulations as we interpreted
15 them, DEA could pull our license and
16 then we would all be unemployed.
17 QUESTIONS BY MR. GOTTO:
18 Q. And did you also understand or
19 did you -- did you have a view as to the
20 potential for any harm that could result from
21 diversion of the narcotic products?
22 MR. DAVISON: Objection to
23 form.
24 THE WITNESS: Yes.
25

Page 81

1 QUESTIONS BY MR. GOTTO:
2 Q. And what was that?
3 A. Well, having worked for the
4 police department for 17 years, I'd had
5 face-to-face contact with drug abusers. And
6 just hearing things on the news and that, it
7 was apparent that when it gets in the wrong
8 hands, the outcome is not good.
9 Q. So you had an appreciation for
10 the potential for abuse of these products?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: Yes.
14 QUESTIONS BY MR. GOTTO:
15 Q. So focusing on the dosage
16 business, tell me the steps that were taken
17 by the customer service department during the
18 period you had responsibility for dosage to
19 prevent diversion.
20 A. The customer service reps,
21 their responsibility ended with the entry of
22 the 222 form number on the order to allow it
23 to print in Hobart for preparation.
24 Once it printed in Hobart, then
25 the onus was on the Hobart facility to ensure

Page 82

1 from that point forward that the product was
2 protected.
3 Q. Okay. So am I understanding
4 your answer that it was the entry of the 222
5 form, that was the action taken by the
6 customer service department to prevent
7 diversion?
8 A. Correct.
9 MR. DAVISON: Objection to
10 form.
11 QUESTIONS BY MR. GOTTO:
12 Q. Okay. During the period when
13 you had planning responsibilities that
14 extended to narcotics, did you personally or
15 did anyone under your supervision have any
16 responsibility with respect to the avoidance
17 or prevention of diversion?
18 MR. DAVISON: Objection to
19 form.
20 THE WITNESS: No.
21 QUESTIONS BY MR. GOTTO:
22 Q. During the period when you had
23 responsibility for the -- for API as customer
24 service -- and I'm sorry, was your title
25 customer service manager?

Page 83

1 A. Yes.
2 Q. Okay. So during that period
3 when you were customer service manager for
4 API, tell me the steps that the customer
5 service department went through to prevent
6 diversion.
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: It would have
10 been the same as on the dosage side:
11 entry of a valid 222 form number in
12 the order, and once it printed at the
13 St. Louis plant, then they were
14 responsible for securing the shipment
15 from that point forward.
16 QUESTIONS BY MR. GOTTO:
17 Q. Okay. Focusing back on the
18 dosage period of -- when you were customer
19 service manager, do you recall any occasions
20 when it came to your attention that any
21 product may have been diverted?
22 A. Yes.
23 Q. What can you recall in that
24 regard?
25 A. We had an occasion where one of

Page 84

1 our couriers, I don't recall if it was FedEx
2 or UPS, had become so familiar with his route
3 that he figured out that he was delivering
4 methadone to a clinic, and he stole one of
5 the packages.
6 Q. Okay. And how did you become
7 aware of that?
8 A. It was reported to us by the
9 methadone clinic because they needed a credit
10 for the shortage on their order, and then we
11 had to -- not we, customer service, but then
12 Mallinckrodt had a group to investigate.
13 Q. Okay. Any other occasions
14 where you became aware of diversion?
15 A. No.
16 Q. Okay. How about when you had
17 responsibility for the API business as
18 customer service manager, were there any
19 occasions where you became aware of
20 diversion?
21 A. I don't ever recall an API
22 diversion.
23 Q. Okay. Are you familiar with
24 the term "suspicious order monitoring"?
25 A. Yes, I am.

Page 85

1 Q. What does that mean to you?
2 A. It was an initiative by DEA to
3 have manufacturers ensure that customers
4 weren't trying to circumvent the system to
5 obtain more product than was normally their
6 order quantity.
7 Q. And do you recall when DEA
8 commenced that initiative?
9 A. No.
10 Q. Do you recall if the
11 commencement of that initiative was prior to
12 the time that you became customer service
13 manager?
14 A. I don't recall.
15 Q. Do you recall being involved in
16 any steps taken at Mallinckrodt to comply
17 with that DEA initiative?
18 A. Yes.
19 Q. And what can you recall in that
20 regard?
21 A. I was on the team that worked
22 with the programming group to develop
23 algorithms to help us identify orders that
24 might be suspicious so we could investigate
25 them prior to the order being released to the

Page 86

1 distribution center.
2 Q. Who else can you remember being
3 on that team?
4 A. Karen. Jim Rausch, I believe,
5 was on it. A couple programmers. And then
6 there was some ad hoc people that weren't
7 actually in all the meetings every day, but
8 we'd report to them what we were doing.
9 Q. Do you recall when that team
10 was first formed?
11 A. It was after I attended a DEA
12 conference with Karen up in Washington, DC.
13 I don't remember the exact date.
14 Q. Okay. And do you recall how
15 long that team stayed in place?
16 A. It's quite a while. I don't
17 remember exactly.
18 Q. Did the team ultimately develop
19 one or more algorithms to become part of the
20 suspicious order monitoring process?
21 A. Yes. Yes.
22 Q. And do you recall approximately
23 when those algorithms were completed and
24 implemented?
25 A. No.

Page 87

1 Q. And was there any sort of
2 memorandum or report or other document
3 prepared by the team to memorialize the
4 output of its work?
5 A. I don't recall.
6 Q. So the algorithms that were
7 developed, where would they be housed?
8 MR. DAVISON: Objection to
9 form.
10 THE WITNESS: I would --
11 explain, please.
12 QUESTIONS BY MR. GOTTO:
13 Q. Sure.
14 If I wanted to see them, where
15 would I look for them?
16 A. I would say in the
17 documentation that the programmers had. You
18 had to submit these forms that would be
19 specific in what you needed, how often it
20 needed to run, that type of thing. So I
21 would say they would have the document that
22 had all of the final -- as it is now and the
23 prior iterations as adjustments were made.
24 Q. Okay. Did you personally
25 maintain any files that reflected the work

Page 88

1 that the team performed?
2 A. Yes.
3 Q. And what can you recall
4 retaining in those files?
5 A. Just my general notes about
6 what things we wanted to look for that we
7 thought -- we were trying to make something
8 that was very robust, and so just our thought
9 process as we worked through all of these
10 steps to come up with a program.
11 Q. Okay. Do you recall if the
12 files that you personally maintained included
13 the ultimate algorithms themselves that were
14 developed?
15 A. No.
16 Q. I asked a bad question.
17 So do you -- did -- was your
18 answer that you don't recall, or was your
19 answer that your files did not include those
20 materials?
21 A. I don't recall.
22 Q. Okay. Fair enough.
23 You mentioned a DEA conference
24 that you and Ms. Harper attended in DC.
25 A. Correct.

Page 89

1 Q. Did you attend any other
2 external conferences or other training
3 sessions in connection with your work on the
4 suspicious order monitoring team?
5 A. No.
6 Q. Okay. Did you participate in
7 any consultation with any outside service
8 provider that you can recall with respect to
9 the suspicious order monitoring team's work?
10 A. I did not.
11 Q. And again, in connection with
12 the suspicious order monitoring team, did you
13 review any materials from any source that
14 described steps taken by other manufacturers
15 to comply with the DEA suspicious order
16 monitoring initiative?
17 A. I do recall having some
18 conversations with manufacturers at the
19 conference, but not after.
20 Q. Okay. The DEA conference that
21 you can recall in DC, was it actually
22 conducted by the DEA?
23 A. It was conducted by Buzzeo, and
24 I -- I don't know, I don't recall what his
25 role was. I don't know if he was former DEA

<p style="text-align: right;">Page 90</p> <p>1 or what, but he hosted conferences on 2 occasion. 3 Q. Were one or more individuals 4 from the DEA present to make presentations at 5 that conference? 6 A. I believe so. 7 Q. Did you receive any materials 8 from that conference? 9 A. Most of it was verbal. I don't 10 recall receiving any formal documentation 11 from DEA. 12 Q. Okay. Or from anyone else at 13 the conference? 14 A. Or from -- no. 15 Q. Okay. Do you recall -- well, 16 let's talk for a moment about the team, the 17 Mallinckrodt team, on the -- can we just call 18 it the SOM for short? 19 A. Yep. 20 Q. Okay. Did anyone else on the 21 team report back to the team at any point 22 with respect to any conference or other 23 training that they had attended that provided 24 information that was relevant to the team's 25 activities?</p>	<p style="text-align: right;">Page 92</p> <p>1 meeting to be extended. 2 Q. Okay. So meetings that were 3 not extended, what would be their approximate 4 duration? 5 A. Oh, maybe half an hour, 6 45 minutes. 7 Q. Okay. Was there any formalized 8 process of keeping minutes or notes of the -- 9 of the team's meetings? 10 A. I do believe somebody did, but 11 I don't recall who. I just kept my personal 12 notes. 13 Q. Okay. And did you keep -- 14 retain those personal notes in your file? 15 A. Yes. 16 Q. Okay. So as far as you know, 17 your files at Mallinckrodt -- well, back up. 18 When you retired from 19 Mallinckrodt, did you take any of your files 20 with you that you had maintained at work? 21 A. No. When I moved out of that 22 position, I left the files for Bonita or 23 whoever came in behind me so they'd have them 24 for reference. 25 Q. And the files as you left them</p>
<p style="text-align: right;">Page 91</p> <p>1 MR. DAVISON: Objection to 2 form. 3 THE WITNESS: Not that I 4 recall. 5 QUESTIONS BY MR. GOTTO: 6 Q. Okay. And did the team ever 7 consult with any non-Mallinckrodt personnel? 8 MR. DAVISON: Objection to 9 form. 10 THE WITNESS: Not that I know 11 of. 12 QUESTIONS BY MR. GOTTO: 13 Q. Did the team meet regularly? 14 A. Yes. 15 Q. About how frequently? 16 A. I don't recall exactly. 17 Possibly every other week. 18 Q. Okay. And were they lengthy 19 meetings? Do you recall anything about the 20 approximate duration? 21 A. There were a couple there were 22 lengthy as we got into in-depth conversations 23 with IT about whether or not something that 24 we wanted to do was feasible, but generally 25 that was the only thing that would cause a</p>	<p style="text-align: right;">Page 93</p> <p>1 would have included whatever notes you 2 personally took -- 3 A. Yes. 4 Q. -- from the team's meetings? 5 A. Yes. 6 Q. Okay. And you believe in 7 addition someone may have maintained some 8 sort of formal notes or minutes of the 9 team's -- 10 A. Yes. 11 Q. -- meetings? 12 But you don't know who that is? 13 A. I don't know who, yeah. 14 (Mallinckrodt-Stewart Exhibit 1 15 marked for identification.) 16 QUESTIONS BY MR. GOTTO: 17 Q. Ms. Stewart, we've marked as 18 Exhibit 1 to your deposition a series of two 19 e-mails from April 1 of 2008 and bearing 20 Bates numbers MNK-T1_0000268860. 21 Can you take a look at those 22 e-mails and -- 23 MR. DAVISON: Sorry, I have 24 different -- I just want to make sure 25 we're looking at the same. I have a</p>

Page 94

1 different Bates number. Mine says
2 299558.
3 MR. GOTTO: Okay. I'm sorry.
4 I actually have two versions of the
5 same thing.
6 MR. DAVISON: Okay.
7 MR. GOTTO: And so the one we
8 used -- I knew I paid enough attention
9 to that to get it wrong. It's Bates
10 MNK-T1_0000299558. Thank you.
11 QUESTIONS BY MR. GOTTO:
12 Q. Do you recognize those e-mails?
13 A. I don't recognize them other
14 than they -- I know I received them by virtue
15 of the fact I'm copied on them.
16 Q. Okay. So the bottom e-mail on
17 the page from Mr. Ratliff -- first of all,
18 who was Bill Ratliff, if you recall?
19 A. Bill Ratliff was the director
20 of security for Mallinckrodt --
21 Q. Okay.
22 A. -- and she was -- he was Karen
23 Harper's direct supervisor.
24 Q. Okay. So Mr. Ratliff, on
25 April 1 of '08, sends an e-mail to yourself,

Page 95

1 Mr. Pheney, Mr. Rausch.
2 And Mr. Pheney was your
3 supervisor, correct?
4 A. Correct.
5 Q. Do you know if he was also
6 Mr. Rausch's supervisor?
7 A. Yes, he was.
8 Q. Okay. And copies Karen Harper.
9 And in the e-mail -- he starts
10 it with Jim, so it sounds like he was really,
11 in his mind, anyway, directing this primarily
12 to Mr. Rausch.
13 He mentions Pete Kleissle,
14 K-l-e-i-s-s-l-e, of the DEA diversion group,
15 supervisor, in St. Louis.
16 Do you know who Mr. Kleissle
17 was?
18 A. Yes, I do.
19 Q. Have you ever had any personal
20 interaction with him?
21 A. Yes, I have.
22 Q. And in what regards can you
23 recall that?
24 A. I worked with him at the police
25 department, and once he moved into DEA

Page 96

1 diversion, I had no more dealings with him.
2 Q. Okay. So during your time at
3 Mallinckrodt, you didn't interact with
4 Mr. Kleissle?
5 A. No.
6 Q. Okay. Back to Mr. Ratliff's --
7 is it Ratliff or Ratliff?
8 A. Ratliff.
9 Q. Thank you.
10 Back to Mr. Ratliff's e-mail.
11 He says that Mr. Kleissle just
12 called regarding several letters he has
13 received from you detailing suspicious
14 orders. He advised that he needs more
15 information in that if it is suspicious, why
16 are we filling the order.
17 "I explained that we use a
18 calculation based upon an amount previously
19 ordered."
20 He stated, "If you think it's
21 suspicious, don't fill it. I will go into
22 more detail on Friday."
23 He then goes on to say, "In
24 addition, I advise that we have a conference
25 call planned with Frank Sapienza,

Page 97

1 S-a-p-i-e-n-z-a, on Friday to strengthen our
2 suspicious order identification system."
3 Do you see that?
4 A. Yes, I do.
5 Q. So let me start: Do you know
6 who Mr. Sapienza was?
7 A. I don't know him personally. I
8 understand he was affiliated with the DEA.
9 Q. Okay. And do you recall ever
10 participating on a conference call with him?
11 A. No.
12 Q. Okay. Do you have any
13 recollection with respect to receiving any
14 report of the result of the conference call
15 that Mr. Ratliff mentions in his April 1
16 e-mail?
17 A. No.
18 Q. So you don't know if it
19 happened or not?
20 A. No.
21 Q. Now, in response to
22 Mr. Ratliff, Mr. Rausch says, "Bill, okay, I
23 think we just sent the monthly one out
24 yesterday, so maybe that's the one he just
25 got. We won't send out any more."

Page 98

1 Correct?

2 A. Correct.

3 Q. And so do you know what

4 Mr. Rausch is referring to there?

5 MR. DAVISON: Objection to

6 form.

7 THE WITNESS: From

8 conversations with Jim at the time,

9 there was a report that was printed

10 out at the end of the month that

11 listed all the orders that were

12 thought to be suspicious. That report

13 was forwarded to DEA. I never had

14 anything to do with the report, but

15 that's my understanding from Jim.

16 QUESTIONS BY MR. GOTTO:

17 Q. Okay. And do you -- do you

18 have an understanding as to how orders were

19 identified for inclusion on that report?

20 A. I don't know.

21 Q. So these e-mails are dated

22 April 1, 2008. And since Mr. Ratliff's

23 initial e-mail is addressed to you and

24 Mr. Rausch and Mr. Pheney, does that indicate

25 to you that by this date you had -- you had

Page 99

1 taken on the customer service responsibility?

2 A. Yes, I would say so.

3 Q. Okay. So at this point you

4 were the customer service manager for dosage;

5 is that fair?

6 MR. DAVISON: Objection to

7 form.

8 THE WITNESS: I believe so.

9 QUESTIONS BY MR. GOTTO:

10 Q. Okay. And is it your

11 understanding that Mr. Rausch was the

12 customer service manager with respect to API

13 at this point?

14 A. I believe so.

15 Q. Okay. So it appears that

16 Mr. Rausch had a process to send monthly

17 reports to DEA with respect to suspicious

18 orders at this point, correct?

19 A. That's my understanding.

20 MR. DAVISON: Objection to

21 form.

22 QUESTIONS BY MR. GOTTO:

23 Q. Did you, as customer service

24 manager for dosage, ever provide a monthly

25 report to DEA?

Page 100

1 A. I did not.

2 Q. Did you ever provide any direct

3 communication to DEA?

4 A. I did not.

5 Q. Are you aware of any direct

6 communications to DEA from someone at

7 Mallinckrodt with respect to dosage

8 specific -- dosage suspicious orders?

9 A. I believe Eileen Spaulding at

10 the Hobart facility did send something to

11 them.

12 Q. And who was Ms. Spaulding?

13 A. Eileen Spaulding was the DEA

14 compliance person for the Hobart plant. She

15 was part of Karen's team but assigned to

16 Hobart, New York.

17 Q. Okay. And you have an

18 understanding that Ms. Spaulding at some point

19 sent a communication of some sort direct to

20 DEA?

21 A. That's my understanding.

22 Q. And what's that understanding

23 based on?

24 A. Just conversation.

25 Q. Do you recall with whom?

Page 101

1 A. No.

2 Q. Okay. Do you have any

3 recollection as to the approximate time frame

4 of that communication?

5 A. No.

6 Q. Was it a single communication?

7 A. I have no idea.

8 Q. Do you have any recollection

9 with respect to any understanding that you

10 had at any point regarding the substance of

11 that communication?

12 A. No.

13 MR. DAVISON: Object to form.

14 QUESTIONS BY MR. GOTTO:

15 Q. Apart from Ms. Spaulding's

16 communication direct with DEA, was there any

17 other direct communication between

18 Mallinckrodt and DEA with respect to

19 dosage-suspicious orders during the period

20 when you were customer service manager with

21 responsibility for dosage?

22 MR. DAVISON: Objection to

23 form.

24 THE WITNESS: Not initially.

25

Page 102

1 QUESTIONS BY MR. GOTTO:
2 Q. Okay. So when you say "not
3 initially," was -- is there some subsequent
4 communication --
5 A. As the process -- as the report
6 evolved, then we -- the intent of the report
7 was if we could not justify or explain why we
8 had an anomaly with the order, then we
9 actually -- we reported it to Karen's group,
10 and then Karen would investigate further and,
11 if necessary, report that to DEA.
12 Q. Okay. And do you know if
13 Karen's group, in fact, reported any such
14 orders to DEA?
15 A. I don't know.
16 Q. Do you know if -- well, when
17 you said "we would refer an order to Karen's
18 group," who is "we"?
19 A. Me.
20 Q. Okay. So can you recall
21 referring one or more orders to Karen's
22 group --
23 A. Yes.
24 Q. -- at any time?
25 And what's the approximate

Page 103

1 number that you can recall referring?
2 A. Oh, not many. One or two,
3 maybe a few more, but there weren't a lot.
4 Q. Okay. Did any -- do you recall
5 any specifics with respect to any of them?
6 A. Some of them would be a
7 customer ordered a large quantity of a
8 product that was in excess of what their
9 historical order quantity was, but we would
10 investigate, and we'd determine that there
11 was a valid reason.
12 Weather played a part in some
13 of our shipments being delayed, so customers
14 would call and -- you know, they didn't get
15 this shipment, but could they -- could we
16 FedEx them something over and above what they
17 had already received. So that would probably
18 pop up on the report.
19 But once we'd investigate, we
20 could explain why they needed the additional
21 product and...
22 Q. Okay. So focusing back on
23 Mr. Ratliff's April 1, '08 e-mail in
24 Exhibit 1, he states, "I explained that we
25 use a calculation based upon an amount

Page 104

1 previously ordered."
2 Do you see that?
3 A. Uh-huh.
4 Q. Do you know what he's referring
5 to there?
6 MR. DAVISON: Objection to
7 form.
8 THE WITNESS: I do not.
9 QUESTIONS BY MR. GOTTO:
10 Q. So during the period when you
11 were customer service manager with
12 responsibility for dosage, do you recall at
13 any point during that period using a
14 calculation based upon amounts previously
15 ordered to determine whether an order may be
16 suspicious?
17 A. Part of the suspicious order
18 monitoring team used a calculation such as
19 that, in addition to others.
20 Q. Okay. So when you say "the
21 suspicious order monitoring team used a
22 calculation," do you mean that was included
23 in the algorithms that the suspicious order
24 monitoring team ultimately produced?
25 A. Yes.

Page 105

1 Q. Okay. And do you recall any
2 specifics of that calculation?
3 A. I do not of this calculation.
4 I have some knowledge of the calculations we
5 proposed to be in the report.
6 Q. And what is that knowledge?
7 A. An accumulative purchase
8 quantity exceeding a prior year's purchase
9 quantity.
10 Timing. If customers typically
11 place orders once a month and suddenly we're
12 getting orders every other week or something
13 like that, that would have popped up on the
14 report.
15 I can't remember what the other
16 ones were, but there were several
17 calculations that we used.
18 Q. Okay. So included among the
19 SOM team's recommended algorithms was a
20 comparison of the volume of a given order to
21 some sort of historical average; is that
22 fair?
23 A. Correct.
24 Q. And do you recall if there was
25 a particular level at which an increase would

Page 106

1 trigger further inquiry?
2 A. There was discussion about, you
3 know, is it two times or three times. I
4 don't recall what the final number was.
5 Q. Do you recall if there was a
6 final number?
7 A. I don't recall.
8 Q. Do you recall having any
9 personal input into the determination of what
10 that final number would be?
11 A. No.
12 Q. Do you recall who on the team
13 expressed any view as to what that final
14 number should be?
15 A. No.
16 Q. Do you recall anyone on the
17 team giving any indication as to whether a
18 similar analysis had been employed
19 historically?
20 A. No.
21 Q. Do you recall ever seeing any
22 of the monthly reports that Mr. Rausch sent
23 to DEA?
24 A. No, I did not.
25 Q. In looking back at

Page 107

1 Mr. Ratliff's e-mail of April 1, he concludes
2 the first paragraph by saying, "I will go
3 into more detail on Friday."
4 Do you see that?
5 A. Uh-huh.
6 Q. Do you recall if you
7 participated in any conversations with
8 Mr. Ratliff the following Friday on this
9 topic?
10 A. I don't recall.
11 Q. Okay. Set that aside.
12 (Mallinckrodt-Stewart Exhibit 2
13 marked for identification.)
14 QUESTIONS BY MR. GOTTO:
15 Q. Ms. Stewart, we've marked as
16 Exhibit 2 a one-page document -- I'm sorry,
17 it's actually two pages because it's front
18 and back -- encaptioned "Peculiar Order
19 Process," and beginning at Bates
20 MNK-T1_0000268717.
21 Does that document look
22 familiar to you at all?
23 A. No.
24 Q. Do you recognize the
25 handwriting on the document?

Page 108

1 A. No.
2 Q. The caption is "Peculiar order
3 process."
4 Is "peculiar order" a term that
5 you have any familiarity with?
6 A. Yes.
7 Q. And what's that familiarity?
8 A. There was some discussion about
9 whether calling the report suspicious was
10 appropriate, so the option was suggested that
11 we call it peculiar because it was out of the
12 ordinary, but that would -- until it was
13 investigated and determined, it would not be
14 called suspicious.
15 Q. Okay. And were these
16 discussions at the SOM team?
17 A. Yes.
18 Q. Okay. And was that because
19 suspicious order was a DEA term, that a
20 suspicious order --
21 A. Yes.
22 Q. -- should not be filled?
23 A. Right.
24 Q. So peculiar order was a term
25 you used at Mallinckrodt?

Page 109

1 A. Yeah. Right.
2 Q. Okay. In the middle of that
3 page, there's some numbered paragraphs.
4 Do you see them?
5 A. Yes.
6 Q. And there's a paragraph 1 that
7 discusses "an order will be considered
8 peculiar if the order quantity for a SKU,
9 when converted to equivalent API, is two
10 times the average API for that SKU/DEA
11 reporting class and customer combination.
12 The historical rolling average calculation
13 that will be used for established customers
14 will be 7 to 18 months."
15 Did I read that correctly?
16 A. Yes.
17 Q. And is that the sort of
18 quantitative comparison of the order to
19 historical that you testified about earlier?
20 MR. DAVISON: Objection to
21 form.
22 THE WITNESS: That's my
23 understanding.
24 QUESTIONS BY MR. GOTTO:
25 Q. Okay. Do you recall that

Page 110

1 particular measure, two times the 7- to
2 18-month rolling average, being something
3 that was discussed by the team?
4 A. I remember the portion of
5 converting the SKUs to equivalent API for the
6 calculation. I don't recall, per se, the two
7 times average.
8 Q. Okay. And do you know if that
9 measure as described in paragraph 1 on this
10 document was, in fact, the measure that was
11 incorporated into the team's ultimate
12 algorithms?
13 A. I don't know that.
14 Q. And paragraph 3 says, "Peculiar
15 orders will be put on hold immediately after
16 being entered."
17 Do you see that?
18 A. Yes.
19 Q. And do you recall if that was
20 part of the team's ultimate output in terms
21 of suspicious order monitoring?
22 A. Yes.
23 Q. And if a -- during the time
24 when you had responsibility for dosage, were
25 there any peculiar orders that were put on

Page 111

1 hold that you can recall?
2 A. Not specifically that I can
3 recall.
4 Q. Okay. How about during the
5 time you had responsibility for API as
6 customer service manager?
7 A. No.
8 Q. Okay. So fair to say that
9 during the entire time you were customer
10 service manager you don't recall any peculiar
11 order being put on hold?
12 A. Correct.
13 Q. Do you recall any circumstances
14 in which a peculiar order was filled prior to
15 the time a determination had been made as to
16 whether it was suspicious?
17 A. I don't recall.
18 Q. And that would apply both to
19 when you had responsibility for dosage and
20 for API?
21 A. Correct.
22 Q. Okay. Paragraph 4 says,
23 "Dosage will get a peculiar order report
24 twice a day. Bulk will get the report once a
25 day."

Page 112

1 Ultimately, do you recall if
2 that process was adopted?
3 A. Yes.
4 Q. And so during the period you
5 were customer service manager for dosage, did
6 you receive a peculiar order report twice a
7 day?
8 A. Yes.
9 Q. Approximately how many peculiar
10 orders can you recall being included on a
11 peculiar order report?
12 A. I have --
13 MR. DAVISON: Objection to
14 form.
15 THE WITNESS: I don't know.
16 Not many, but I can't specify a
17 number.
18 QUESTIONS BY MR. GOTTO:
19 Q. Okay. But you would receive
20 the report twice a day, correct?
21 A. Yes.
22 Q. Were there times when the
23 report had no peculiar orders on it?
24 A. I don't recall.
25 Q. Okay. Would it be unusual if a

Page 113

1 peculiar order report that you received with
2 respect to dosage had more than ten orders on
3 it?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: I don't know.
7 QUESTIONS BY MR. GOTTO:
8 Q. Okay. Would it be unusual if
9 it had more than 20 on it, 20 orders?
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: I don't ever
13 recall a report having that many.
14 QUESTIONS BY MR. GOTTO:
15 Q. Okay. So as best you can
16 recall today, it would be unusual if it had
17 more than 20?
18 A. Yes. Yeah.
19 Q. But you don't recall if it
20 would be unusual if it had more than ten?
21 MR. DAVISON: Objection.
22 THE WITNESS: I don't recall it
23 ever having more than ten.
24 QUESTIONS BY MR. GOTTO:
25 Q. Okay. Do you recall a report

Page 114

1 having more than five orders on it?
 2 A. I don't recall.
 3 Q. May have or may not --
 4 A. May have, yeah.
 5 Q. You just don't know?
 6 A. I just don't know.
 7 Q. Okay. So if you received the
 8 report twice a day, you received ten reports
 9 a week, right?
 10 A. Correct.
 11 Q. On a typical five-day workweek?
 12 A. Yes.
 13 Q. So is it fair to conclude that
 14 over the course of a typical five-day
 15 workweek you would have received peculiar
 16 order reports indicating -- you know,
 17 reporting some number of peculiar orders for
 18 that week?
 19 MR. DAVISON: Objection to
 20 form.
 21 THE WITNESS: Correct.
 22 QUESTIONS BY MR. GOTTO:
 23 Q. So when you received a peculiar
 24 order report that identified one or more
 25 peculiar orders, what steps did you take with

Page 115

1 respect to that order?
 2 A. I investigated in the sense
 3 that who was the customer, what were the
 4 circumstances, if I knew of them. We had
 5 instances in snowstorms where trucks got
 6 stuck for days at a time on a highway. And
 7 so if I knew of a circumstance that justified
 8 the reason for the additional order, or the
 9 peculiar order, then I'd discuss it with
 10 Karen and we would release the order. If
 11 not, we kind of kicked it up the chain and
 12 said, "I can't figure out why they're
 13 ordering this," and then Karen would maybe
 14 get with marketing or whatever to resolve the
 15 problem.
 16 Q. Okay. So once an order was
 17 identified as peculiar -- and again, focusing
 18 on dosage initially -- who had the authority
 19 to authorize the filling of that order?
 20 A. I did.
 21 Q. Okay.
 22 A. Or Karen, Bill Ratliff.
 23 Q. Okay.
 24 A. Any one of us.
 25 Q. Okay. Were there times that

Page 116

1 you can recall authorizing the fulfilment of
 2 an order that had been identified as peculiar
 3 without consulting with anyone else?
 4 A. Yes.
 5 Q. And what circumstances can you
 6 recall?
 7 A. I can't remember.
 8 Q. Okay. May have been, for
 9 example, the weather-related type thing that
 10 you described?
 11 A. Right. Yes.
 12 Q. Do you ever recall a
 13 circumstance, again, focusing on dosage,
 14 where someone else, Ms. Harper or someone
 15 else in the -- in the chain, authorized the
 16 fulfilment of a peculiar order where you had
 17 concerns that the issue as to whether it was
 18 suspicious had not been thoroughly
 19 investigated?
 20 A. No.
 21 Q. Now, let's turn to when you had
 22 responsibility for API.
 23 A. Uh-huh.
 24 Q. Did you receive the report once
 25 a day --

Page 117

1 A. Yes.
 2 Q. -- during that time?
 3 A. Yes.
 4 Q. Okay. And typically was there
 5 at least one order reflected on a report?
 6 A. I would say not daily, but
 7 maybe over the course of a week there might
 8 be a report, an order on the report.
 9 Q. Okay. With respect to any
 10 order that was reported as peculiar on the
 11 bulk report, what steps would you take?
 12 A. The same as with dosage.
 13 Q. And did the same people have
 14 authority to authorize the fulfilment of a
 15 bulk order that had been identified as
 16 peculiar as had that authority with respect
 17 to dosage?
 18 A. Yes.
 19 Q. Do you know if there was -- or
 20 do you recall there being any occasion in
 21 which a bulk order was fulfilled -- a bulk
 22 order that had been identified as peculiar
 23 was fulfilled prior to the time a final
 24 determination had been made as to whether it
 25 was suspicious?

Page 118

1 A. No.

2 Q. Below paragraph 4 on Exhibit 2,

3 there's a caption -- a paragraph encaptioned

4 "New Customers for Dosage."

5 Do you see that?

6 A. Uh-huh.

7 Q. And that paragraph discusses

8 establishing a threshold for new customers.

9 Do you recall that being a

10 matter that the SOM team addressed?

11 A. Yes.

12 Q. And you can just read that

13 paragraph to yourself, but tell me if your

14 recollection is that the -- the procedure

15 described in that paragraph is what the SOM

16 team ultimately adopted.

17 A. To the best of my recollection

18 it is.

19 Q. Okay. Similar questions for

20 the following paragraph concerning bulk new

21 customers.

22 A. Yes.

23 Q. Okay. So best of your

24 recollection, that's the procedure that was

25 adopted?

Page 119

1 A. Uh-huh.

2 Q. Okay. Okay. You can put that

3 aside.

4 MR. DAVISON: We've been going

5 about another hour. Do you mind if we

6 take a break?

7 MR. GOTTO: Sure.

8 MR. DAVISON: Is now a good

9 time?

10 MR. GOTTO: You bet. Go off

11 the record.

12 VIDEOGRAPHER: We're going off

13 the record at 11:22 a.m.

14 (Off the record at 11:22 a.m.)

15 VIDEOGRAPHER: We are back on

16 the record at 11:38 a.m.

17 (Mallinckrodt-Stewart Exhibit 3

18 marked for identification.)

19 QUESTIONS BY MR. GOTTO:

20 Q. Ms. Stewart, we've just handed

21 you what we've marked as Exhibit 3, which is

22 a three-page document bearing Bates beginning

23 on MNK-T1_0000268710, and its encaptioned

24 "Peculiar Order Process For Bulk API" and has

25 a handwritten date on of it 4/15/09.

Page 120

1 Do you recognize that

2 handwriting?

3 A. No, I do not.

4 Q. Okay. At 4/15/09, this would

5 have been a period when you had customer

6 service responsibility for dosage, correct?

7 A. Correct.

8 Q. Do you recall if there was a

9 different peculiar order process for bulk as

10 compared to dosage?

11 A. I do not know. I don't recall.

12 Q. Okay. In paragraph 3 on the

13 first page of Exhibit 3 it states, "The

14 program should only look at customers, paren,

15 ship to, close parens, with an SN customer

16 search type."

17 Do you know what SN customer

18 service type is?

19 A. I don't recall the customer

20 search type codes anymore.

21 Q. Okay. And paragraph 5 says,

22 "The bulk peculiar order report should

23 capture orders that are two times the average

24 quantity of the SKU and customer, paren, ship

25 to, close paren, combination over the

Page 121

1 historical sales average up to 18 months,

2 parens, rolling, close parens."

3 Do you see that?

4 A. Yes, I do.

5 Q. And do you recall if that

6 measurement was in place for the peculiar

7 order report for API during the period that

8 you had customer service responsibility for

9 API?

10 A. I don't recall.

11 Q. Section B on page 1 of

12 paragraph 3 talks about peculiar order report

13 for new customers.

14 Do you see that?

15 A. Yes.

16 Q. Did the customer service

17 department have any role to play in whether a

18 new customer was accepted for purposes of

19 receiving narcotic shipments?

20 A. No. We had a group called

21 customer data integrity, and they worked with

22 marketing to set up new customer accounts.

23 Q. Okay. So during your period at

24 the -- with customer service responsibility,

25 did you have any personal responsibilities

Page 122

1 that extended to determining whether a new
2 customer should be accepted?
3 A. No.
4 Q. Okay. If you turn to the
5 second page of paragraph 3 -- of Exhibit 3,
6 heading C talks about orders of unusual
7 frequency.
8 Do you see that?
9 A. Yes.
10 Q. And there are five paragraphs
11 that discuss the issue, and I won't go
12 through them specifically. But my question
13 for you is, during the period that you had
14 responsibility for API as customer service
15 manager, do you recall orders being
16 identified as peculiar because of unusual
17 frequency?
18 A. I don't recall.
19 Q. Okay. Section D later on in
20 that page talks about irregular order pattern
21 report.
22 Do you see that?
23 A. Yes.
24 Q. Okay. And there are three
25 numbered paragraphs under that heading, and

Page 123

1 again, you can feel free to review those if
2 you like.
3 My question for you is, during
4 the period that you had responsibility for
5 API as customer service manager, do you
6 recall any orders being identified as
7 peculiar because of an irregular order
8 pattern?
9 A. I don't recall.
10 Q. And then heading D on the
11 bottom of page 2 and on to page 3 of
12 Exhibit 3 talks about incremental increase
13 violation.
14 Do you see that?
15 A. Yes.
16 Q. And again, during your period
17 as customer service manager with respect to
18 API, do you recall any orders being
19 identified as peculiar because of the
20 incremental increase violation?
21 A. No, I do not.
22 Q. Now, you do recall that there
23 were at least some orders identified as
24 peculiar during the period you had
25 responsibility for API, correct?

Page 124

1 A. Correct.
2 Q. And so do you have any
3 recollection as to the circumstances that
4 caused any of those orders to be identified
5 as peculiar?
6 A. I do not.
7 Q. Okay. You can set that aside.
8 (Mallinckrodt-Stewart Exhibit 4
9 marked for identification.)
10 QUESTIONS BY MR. GOTTO:
11 Q. Ms. Stewart, we've marked as
12 Exhibit 4 a two-page document beginning at
13 Bates MNK-T1_0000302241 that's encaptioned
14 "Peculiar Order Process for Specialty
15 Pharmaceuticals."
16 Do you see that?
17 A. Yes.
18 Q. Do you have an understanding
19 what the phrase "specialty pharmaceuticals"
20 means?
21 A. Yes.
22 Q. What does it mean?
23 A. Narcotics.
24 Q. Okay. And so is specialty
25 pharmaceuticals, does that encompass both

Page 125

1 dosage and API?
2 A. It's my understanding that it
3 typically referred to bulk, but it could have
4 referred to dosage as well. I don't recall
5 exactly.
6 Q. Okay. This document under
7 heading A, peculiar order report for
8 established customers, paragraph 2 says,
9 "Threshold limits should be based upon the
10 customer ship to account if classified as a
11 wholesaler or retailer."
12 Do you recall customers being
13 classified as wholesaler or retailer?
14 A. I do.
15 Q. And would that extend to both
16 API and dosage customers?
17 A. No. Dosage only.
18 Q. Okay. Were there other
19 categorizations of dosage customers other
20 than wholesaler or retailer?
21 A. I believe there were.
22 Q. What can you recall?
23 A. Distributors. There were
24 several classifications. I can't remember
25 all of them.

<p style="text-align: right;">Page 126</p> <p>1 Q. Okay. We spoke a little 2 earlier today about distributors. Do you 3 have an understanding as to the distinction 4 between a wholesaler and a distributor? 5 A. No. 6 Q. Okay. But you do recall that 7 there were separate classifications -- 8 A. Yes. 9 Q. -- for wholesalers and 10 distributors? 11 A. Yes. 12 Q. Do you recall any examples of 13 customers who were categorized as 14 wholesalers? 15 A. No. 16 Q. If you look at paragraph 3 17 under heading A, it says, "For distributors 18 and clinics, a new table will be set up by 19 Cathy Stewart breaking down the distributors 20 into three segments, parens, large, medium 21 and small, and clinics into two segments. 22 Each ship to account will be assigned to one 23 of these segments. A new field will have to 24 be set up in the customer master for these 25 new segment classifications."</p>	<p style="text-align: right;">Page 128</p> <p>1 regarding any discussions about whether such 2 a new table should be created or the reasons 3 for it? 4 A. Correct. 5 Q. Okay. Paragraph 4 under 6 heading A says, "The specialty pharmaceutical 7 peculiar order report for established 8 customers should capture orders that are two 9 times the threshold limits based upon the 10 criteria outlined above." 11 Do you see that? 12 A. Yes. 13 Q. And is that consistent with 14 your recollection of the comparator that was 15 employed with respect -- comparing a given 16 order to historical averages for purposes of 17 whether that order would be included on the 18 peculiar order report? 19 MR. DAVISON: Objection to 20 form. 21 THE WITNESS: There were 22 multiple parameters suggested. I 23 don't recall the two times being the 24 one that was ultimately chosen. 25</p>
<p style="text-align: right;">Page 127</p> <p>1 Do you see that? 2 A. Yes. 3 Q. Do you recall creating such a 4 table? 5 A. I do not. 6 Q. Do you recall making -- taking 7 any steps to subclassify distributors small, 8 medium, large, or any other type of 9 classification? 10 A. No, I don't. 11 MR. DAVISON: Objection to 12 form. 13 QUESTIONS BY MR. GOTTO: 14 Q. Now, that language, the 15 language regarding new table, is underlined 16 on this document, which may indicate that 17 perhaps it was a revision to a prior draft. 18 Is that what that would 19 indicate to you? 20 MR. DAVISON: Objection to 21 form. 22 THE WITNESS: I don't know. 23 QUESTIONS BY MR. GOTTO: 24 Q. Okay. But as you sit here 25 today, you don't have any recollection</p>	<p style="text-align: right;">Page 129</p> <p>1 QUESTIONS BY MR. GOTTO: 2 Q. Okay. Under heading B toward 3 the bottom of the first page of Exhibit 4, in 4 paragraph 1 it says, "New customer ship to 5 accounts are identified as customers who have 6 zero days to six months of sales history. 7 Cathy Stewart needs to decide if specialty 8 pharmaceuticals needs to review every order 9 for new customers or if a new field will be 10 created on the customer master to allow a 11 manual threshold limit number to be entered 12 for the ship to account." 13 Do you see that? 14 A. I do. 15 Q. Do you recall ever making that 16 decision? 17 A. No, I don't. 18 Q. Do you recall ever considering 19 that issue? 20 A. No, I don't. 21 Q. Again, the -- most of that 22 sentence, other than your name, is 23 underlined. 24 Do you have any understanding 25 as to who would have caused that -- that</p>

Page 130

1 sentence to be included in this document?

2 MR. DAVISON: Objection to

3 form.

4 THE WITNESS: No. No, I don't.

5 QUESTIONS BY MR. GOTTO:

6 Q. On the second page of

7 Exhibit 4, heading C, Orders of Unusual

8 Frequency, do you recall during the period

9 that you were customer service manager with

10 responsibility for dosage if any orders were

11 identified as peculiar on the basis of

12 unusual frequency?

13 A. I don't recall.

14 Q. Okay. And heading D, down

15 below on the second page of Exhibit 4, talks

16 about irregular order pattern.

17 Do you see that?

18 A. Yes.

19 Q. And again, during the period

20 you were customer service manager with

21 responsibility for dosage, do you recall any

22 orders being identified as irregular --

23 identified as peculiar because of an

24 irregular order pattern?

25 A. I do not know. Do not recall.

Page 131

1 Q. And back to the first page of

2 Exhibit 4, during the period you were

3 customer service manager with responsibility

4 for dosage, do you recall any orders being

5 identified as peculiar because they exceeded

6 the threshold amount multiplied by the

7 applicable factor?

8 A. I don't recall.

9 Q. But in any event, you do recall

10 there being some orders identified as

11 peculiar, some dosage orders identified as

12 peculiar?

13 A. Yes.

14 Q. Okay. You can set that aside.

15 (Mallinckrodt-Stewart Exhibit 5

16 marked for identification.)

17 QUESTIONS BY MR. GOTTO:

18 Q. Ms. Stewart, we've marked as

19 Exhibit 5 a multi-page document beginning at

20 Bates MNK-T1_0000299578. Appears to be a

21 PowerPoint presentation concerning a DEA

22 pharmaceutical industry conference, September

23 11th of 2007.

24 Take a moment to look through

25 that document. Tell me if you -- if you

Page 132

1 recognize it.

2 A. Okay.

3 Q. Do you recognize that document?

4 A. I do not.

5 Q. Okay. Do you know if you

6 attended the program that is described as

7 having occurred on September 11, 2007?

8 MR. DAVISON: Object to form.

9 THE WITNESS: I don't recall.

10 QUESTIONS BY MR. GOTTO:

11 Q. Do you know who

12 AmerisourceBergen is?

13 A. I do.

14 Q. Who are they?

15 A. They were one of our customers.

16 I believe they're a distributor.

17 Q. Okay. Do you know if anyone

18 else from Mallinckrodt attended this program?

19 A. I don't --

20 MR. DAVISON: Objection to

21 form.

22 THE WITNESS: I don't know.

23 QUESTIONS BY MR. GOTTO:

24 Q. Do you know if anyone, as part

25 of the SOM team that you described, ever

Page 133

1 reported to the team any information that

2 that person had learned at an

3 AmerisourceBergen conference?

4 A. I don't know.

5 Q. Take a look at the second page

6 of Exhibit 5, the regulatory responsibility

7 slide at the bottom of that page.

8 Do you see it?

9 A. Uh-huh.

10 Q. It quotes Title 21 of the Code

11 of Federal Regulations, Section 1301.74 B as

12 follows: "The registrant shall design and

13 operate a system to disclose to the

14 registrant suspicious orders of controlled

15 substances. The registrant shall inform

16 field diversion office of the administration

17 in his area of suspicious orders when

18 discovered by the registrant."

19 Do you see that?

20 A. Yes.

21 Q. And did you understand during

22 the period of -- that you had customer

23 service -- customer service management

24 responsibility, both for dosage and for API,

25 that the obligations described in

Page 134

1 Section 1301.74 B, as quoted on page 2 of
 2 Exhibit 5, applied to Mallinckrodt?
 3 A. Yes.
 4 Q. And did you understand the work
 5 that the SOM team was conducting to be part
 6 of Mallinckrodt's efforts to design and
 7 operate a system to disclose suspicious
 8 orders as described in 1301.74 B of the CFR?
 9 A. I believe so.
 10 Q. And do you know what system
 11 Mallinckrodt had in place to -- well, strike
 12 that.
 13 Do you know what system
 14 Mallinckrodt had designed or operated prior
 15 to the work done by the SOM team to disclose
 16 suspicious orders of controlled substances?
 17 A. I don't know of any formal
 18 protocols, but the customer service reps knew
 19 their customers, and when they suspected
 20 something, they brought it to my attention.
 21 Q. Okay. And indeed on page 3 of
 22 Exhibit 5, the slide at the bottom makes
 23 reference to "know your customer due
 24 diligence."
 25 Do you see that?

Page 135

1 A. Yes.
 2 Q. Is that a term you're familiar
 3 with?
 4 A. Yes.
 5 Q. And what do you understand that
 6 to mean?
 7 A. Both when setting up a new
 8 account for a new customer and as the
 9 customer is established, continuing to
 10 understand the nature of the business and any
 11 rises and falls in their sales volumes.
 12 Q. Okay. And is that something --
 13 is that sort of due diligence something that
 14 the customer service representatives that you
 15 supervised performed?
 16 A. Yes.
 17 Q. And did you provide or did
 18 anyone else at Mallinckrodt provide to them
 19 any training with respect to how to perform
 20 that function?
 21 MR. DAVISON: Objection to
 22 form.
 23 THE WITNESS: No, not that I'm
 24 aware of.
 25

Page 136

1 QUESTIONS BY MR. GOTTO:
 2 Q. Was there any sort of handbook
 3 or other printed material that a customer
 4 service representative at Mallinckrodt could
 5 consult with respect to performing that due
 6 diligence function?
 7 A. I don't recall.
 8 Q. On the slide above the one we
 9 were just looking at, under Regulatory
 10 Responsibility, the first bullet item states,
 11 "Reporting suspicious orders to DEA does not
 12 relieve the distributor of the responsibility
 13 to maintain effective controls to prevent
 14 diversion."
 15 Do you see that?
 16 A. Yes.
 17 Q. And during the time you had
 18 customer service manager responsibility at
 19 Mallinckrodt, did you understand that
 20 similarly as to Mallinckrodt, reporting
 21 suspicious orders to DEA did not relieve
 22 Mallinckrodt of the responsibility to
 23 maintain effective controls to prevent
 24 diversion?
 25 MR. DAVISON: Objection to

Page 137

1 form.
 2 THE WITNESS: Correct.
 3 QUESTIONS BY MR. GOTTO:
 4 Q. You can set that aside.
 5 (Mallinckrodt-Stewart Exhibit 6
 6 marked for identification.)
 7 QUESTIONS BY MR. GOTTO:
 8 Q. We've marked as Exhibit 6
 9 meeting notes from Buzzeo, B-u-z-z-e-o, DEA
 10 conference, October 27 to 30, 2008.
 11 And I believe you testified
 12 earlier today of attending a conference in DC
 13 with Ms. Harper?
 14 A. Correct.
 15 Q. Could you take a look at
 16 Exhibit 6 and tell me if these are -- if this
 17 is that conference that you were recalling
 18 and if these are your notes?
 19 A. Yes. Yes, I did attend this
 20 conference, and, yes, these are my notes.
 21 Q. Great.
 22 And the conference, it states
 23 October 27 to 30.
 24 Was it a four-day conference?
 25 A. I believe so.

Page 138

1 Q. Okay. Did the sessions go on
 2 all day each day?
 3 A. Yes.
 4 Q. Okay. Approximately how many
 5 attendees were at the conference; can you
 6 recall?
 7 A. Oh, I couldn't venture a guess.
 8 Q. Was it more than a hundred
 9 or --
 10 A. Oh, yeah.
 11 Q. Okay.
 12 A. Yes.
 13 Q. Do you remember where it was
 14 held?
 15 A. No.
 16 Q. Okay. And you were there, and
 17 Ms. Harper was there, right?
 18 A. Correct.
 19 Q. Anyone else from Mallinckrodt?
 20 A. No.
 21 Q. Were there a number of
 22 different individuals who made presentations
 23 at this conference?
 24 A. Yes, there were.
 25 Q. And were some of them from the

Page 139

1 DEA?
 2 A. I believe so.
 3 Q. Did anyone from Mallinckrodt
 4 make a presentation?
 5 A. No.
 6 Q. Did anyone from any other
 7 narcotic manufacturer make a presentation
 8 that you can recall?
 9 A. I don't recall.
 10 Q. On page 1 of Exhibit 6 --
 11 MR. DAVISON: Just before you
 12 get into it, I don't know if you read
 13 the document. Just want to make sure
 14 that you've had an opportunity to
 15 review it.
 16 THE WITNESS: Oh, look at it
 17 real quick?
 18 QUESTIONS BY MR. GOTTO:
 19 Q. Yeah, sure. You can look at it
 20 now or you can look at it after I ask a
 21 question.
 22 A. Okay.
 23 Q. If you need to confer, you can
 24 confer. You know, certainly want you to be
 25 familiar with it.

Page 140

1 The first paragraph says,
 2 "Process should include state monitoring
 3 requirements in addition to federal."
 4 Do you see that?
 5 A. I do.
 6 Q. And the process here -- the
 7 heading up above is suspicious order
 8 monitoring, SOM, process, right?
 9 A. (Witness nods head.)
 10 Q. Yes?
 11 A. Yes, it is.
 12 Q. Thanks.
 13 Do you recall if state
 14 monitoring requirements were part of any SOM
 15 process adopted by Mallinckrodt at any time?
 16 MR. DAVISON: Objection to
 17 form.
 18 THE WITNESS: I don't recall.
 19 QUESTIONS BY MR. GOTTO:
 20 Q. Do you recall reviewing -- as
 21 part of the SOM team that you were part of,
 22 do you recall reviewing any particular state
 23 monitoring requirements?
 24 A. No, I don't.
 25 MR. DAVISON: Objection to

Page 141

1 form.
 2 QUESTIONS BY MR. GOTTO:
 3 Q. Okay. The next paragraph
 4 states, "In addition to formalizing the
 5 process to identify suspicious orders prior
 6 to their departure from the DC, we must also
 7 formally document the investigation of each
 8 particular suspicious, parens, peculiar,
 9 close parens, order that gets identified,
 10 including the hows and whys of the logic we
 11 used to deem the order appropriate to ship or
 12 not."
 13 Did I read that correctly?
 14 A. Yes, you did.
 15 Q. What does DC mean?
 16 A. Distribution center.
 17 Q. Okay. And did Mallinckrodt's
 18 SOM process include provision for formally
 19 documenting the investigation of each
 20 suspicious or particular -- or peculiar
 21 order?
 22 MR. DAVISON: Objection to
 23 form.
 24 THE WITNESS: Can you restate
 25 the question?

Page 142

1 QUESTIONS BY MR. GOTTO:
 2 Q. Yes.
 3 Did Mallinckrodt's SOM process
 4 as ultimately adopted include provision for
 5 formally documenting the investigation of
 6 each suspicious or peculiar order?
 7 A. I believe it did.
 8 Q. And what form did that
 9 documentation take?
 10 A. I don't recall. Possibly a --
 11 an internal work order or process, but I
 12 don't recall specifically.
 13 Q. Okay. Is that formal
 14 documentation something that you would have
 15 personally prepared on any occasion?
 16 A. Not for this, I don't believe.
 17 Q. And when you say "not for
 18 this," what's the "this" that you're
 19 referring to?
 20 A. This process.
 21 Q. Okay.
 22 A. Not for the suspicious order
 23 monitoring process.
 24 Q. Okay. Do you know who would
 25 have had responsibility to prepare that

Page 143

1 formal documentation?
 2 A. I don't know.
 3 Q. The one, two, three, four,
 4 fifth paragraph, the one that starts with
 5 "the general consensus," do you see that?
 6 A. Yes.
 7 Q. "The general consensus is that
 8 sales reps are not considered a good option
 9 for on-site investigations and initial review
 10 prior to accepting new customers due to their
 11 perceived bias in getting the customer
 12 approved for sales revenue purposes."
 13 Did I read that correctly?
 14 A. Yes.
 15 Q. Okay. Did Mallinckrodt's SOM
 16 process contemplate sales reps conducting
 17 on-site investigations from time to time?
 18 A. Yes.
 19 MR. DAVISON: Objection to
 20 form.
 21 QUESTIONS BY MR. GOTTO:
 22 Q. Did it contemplate sales reps
 23 participating in the initial review of a
 24 potential new customer?
 25 MR. DAVISON: Objection to

Page 144

1 form.
 2 THE WITNESS: I believe so.
 3 QUESTIONS BY MR. GOTTO:
 4 Q. Okay. The next paragraph says,
 5 "Omnicare has employed two full-time
 6 employees solely for the purpose of auditing
 7 SOM orders."
 8 Do you see that?
 9 A. Yes.
 10 Q. Who was Omnicare?
 11 A. Omnicare is a customer. I
 12 believe they are a distributor.
 13 Q. Customer of Mallinckrodt?
 14 A. Yes.
 15 Q. With respect to narcotics?
 16 A. Yes.
 17 Q. Okay. Did Mallinckrodt employ
 18 any full-time employees solely for the
 19 purpose of auditing suspicious or peculiar
 20 orders?
 21 A. No.
 22 Q. The next paragraph says, "One
 23 supplier indicates that of 13,000 lines per
 24 month, 12 percent, about 1560, were flagged
 25 for SOM purposes."

Page 145

1 Do you see that?
 2 A. Yes.
 3 Q. And when the notes say
 4 "supplier," what does that mean in this
 5 context?
 6 A. One supplier of narcotics to
 7 customers, to their customers.
 8 Q. Okay. It doesn't necessarily
 9 mean someone who supplied Mallinckrodt?
 10 A. No.
 11 Q. Okay.
 12 A. This would be the case where
 13 someone like Mallinckrodt is supplying their
 14 customer.
 15 Q. Okay. And so this supplier --
 16 is it -- does that indicate that there was at
 17 least one supplier that made a presentation
 18 at the conference?
 19 A. I think some of these were
 20 bullet points that the DEA presented.
 21 Q. Okay. So this indicates that
 22 one supplier had experienced about
 23 12 percent -- well, strike that.
 24 When that paragraph says 13,000
 25 lines per month --

Page 146

1 A. Uh-huh.
2 Q. -- what does "lines" mean in
3 this setting?
4 A. Lines would be -- or each
5 molecule strength would be a separate line on
6 an order.
7 Q. Okay. And so this is a
8 supplier that had experienced approximately
9 1560 specific items that were ordered as --
10 that were identified as at least potentially
11 suspicious out of approximately 13,000?
12 MR. DAVISON: Objection to
13 form.
14 THE WITNESS: Correct.
15 Correct.
16 QUESTIONS BY MR. GOTTO:
17 Q. Now, as to Mallinckrodt, in a
18 typical month on the dosage business, how
19 many lines per month would you expect would
20 be ordered?
21 MR. DAVISON: Objection to
22 form.
23 THE WITNESS: I have no idea.
24 A lot.
25

Page 147

1 QUESTIONS BY MR. GOTTO:
2 Q. More than 13,000?
3 A. I don't know. I'd be guessing.
4 Q. Okay. And do you know in terms
5 of Mallinckrodt's experience, as far as
6 orders that were identified as peculiar,
7 whether its experience would approximate the
8 12 percent experience referenced here?
9 MR. DAVISON: Objection to
10 form.
11 THE WITNESS: I don't know.
12 QUESTIONS BY MR. GOTTO:
13 Q. Okay. You didn't personally
14 ever go back and do any sort of calculation
15 as far as what percentage of orders had been
16 identified as peculiar; is that fair?
17 A. Correct.
18 Q. And do you know if anyone else
19 at Mallinckrodt ever performed such a
20 calculation?
21 A. I don't know. In the very
22 beginning it was such a new program, I don't
23 think that anybody was doing it. And by the
24 time it had become an established program, I
25 had moved on, so I don't know if anybody did

Page 148

1 that type of analysis or not.
2 Q. Do you think it's possible that
3 Mallinckrodt's dosage order volumes would
4 have exceeded 13,000 lines per month?
5 MR. DAVISON: Objection to
6 form.
7 THE WITNESS: I would say it's
8 conceivable.
9 QUESTIONS BY MR. GOTTO:
10 Q. During the period that you had
11 responsibility for dosage as customer service
12 manager, do you have any estimate as to the
13 number of peculiar orders that your staff had
14 capacity to evaluate on a daily basis?
15 A. Repeat the question, please.
16 Q. Sure.
17 While you were customer service
18 manager for dosage, do you have any estimate
19 of the number of peculiar orders that the
20 CSRs who reported to you would have capacity
21 to review on a daily basis, approximately?
22 A. My opinion would be that they
23 evaluated every order that they entered for
24 anomalies, and then if they felt that
25 something was out of sort or character,

Page 149

1 they'd bring it to my attention.
2 Q. Okay. So they evaluated --
3 when you say "they evaluated every order," is
4 that independent of whatever algorithms were
5 put in place by the team?
6 A. Yes.
7 Q. And what were the criteria that
8 they used to conduct that evaluation,
9 independent of algorithms?
10 A. Our customer base was -- our
11 relationships had been very long-standing,
12 and the customer service reps were kind of
13 intimate with the customers. They knew
14 exactly what they ordered and what typical
15 quantities were and frequency. So if
16 something seemed out of the ordinary, they
17 would bring it up.
18 Q. Okay. And the -- were the
19 algorithms that the -- that the team adopted
20 in place during any portion of the time that
21 you had dosage responsibility as customer
22 service manager?
23 A. No, they were developed during
24 my tenure in that position.
25 Q. Okay. So during the time you

Page 150

1 had responsibility for dosage, the
 2 identification of orders as peculiar would
 3 have been based entirely on your CSRs making
 4 the sort of evaluation that you just
 5 described a few moments ago?
 6 A. Correct.
 7 MR. DAVISON: Objection to
 8 form.
 9 QUESTIONS BY MR. GOTTO:
 10 Q. A couple of paragraphs below
 11 the one we were just looking at, there's one
 12 that states, "Companies indicate that they
 13 have employed the services of a statistician
 14 to work with their IT professionals to
 15 develop appropriate algorithms, et cetera,
 16 for use in the code to identify the SOM
 17 lines."
 18 Do you see that?
 19 A. Yes.
 20 Q. Did Mallinckrodt, to your
 21 knowledge, ever employ a statistician to work
 22 in this regard?
 23 A. Not that I'm aware of.
 24 Q. If you turn to the second page
 25 of Exhibit 6, the first paragraph, it says,

Page 151

1 "When trying to normalize your data for
 2 purposes of doing calculations to identify
 3 anomalies, consider the base drug, API,
 4 itself, rather than focusing on strengths and
 5 doses per bottle."
 6 Do you see that?
 7 A. Yes.
 8 Q. And did the algorithms that the
 9 team ultimately adopted follow that -- that
 10 direction?
 11 A. Yes, they did.
 12 Q. Okay. Down one, two, three,
 13 four paragraphs from there, there's a
 14 paragraph that says, "Are our customers aware
 15 of the SOM requirements, question mark?
 16 Conduct a prophylactic order" -- I'm sorry --
 17 "prophylactic audit and confirm that they
 18 have systems in place to call out deviations
 19 on orders placed in their systems, paren,
 20 their SOM processes and procedures."
 21 Do you see that?
 22 A. I do.
 23 Q. Did Mallinckrodt ever conduct
 24 such a prophylactic audit?
 25 MR. DAVISON: Objection to

Page 152

1 form.
 2 THE WITNESS: I don't know. I
 3 do know they conducted some audits,
 4 but I don't know if they were
 5 specifically in this regard.
 6 QUESTIONS BY MR. GOTTO:
 7 Q. Okay. Were you -- did you
 8 participate in any such audits?
 9 A. No.
 10 Q. Did you ever receive the
 11 results of any such audits?
 12 A. I don't recall.
 13 Q. The third page of Exhibit 6,
 14 the paragraph right under the word
 15 "hydrocodone" --
 16 A. Yes.
 17 Q. -- says, "Quote, know your
 18 customer, close quote, is not enough anymore.
 19 You must now know your customer's customer as
 20 well. When is a personal visit to that
 21 second-line customer justified and based on
 22 what criteria, question mark?"
 23 During the period that you had
 24 responsibility for dosage as customer service
 25 manager, did anyone at Mallinckrodt, to your

Page 153

1 knowledge, take steps to know Mallinckrodt's
 2 customer's customer?
 3 A. I don't know.
 4 Q. Do you know if any of the CSRs
 5 that you supervised took steps to know the
 6 customer of the customers for whom they had
 7 responsibility?
 8 A. No, we did not have that
 9 information.
 10 Q. The second sentence regarding
 11 personal visit, do you know if anyone at
 12 Mallinckrodt made any such personal visit to
 13 the customer of a Mallinckrodt customer?
 14 A. I'm not aware of any.
 15 Q. Okay. And during the period
 16 that you had responsibility for API as
 17 customer service manager, did anyone, to your
 18 knowledge, at Mallinckrodt take steps to know
 19 Mallinckrodt's customer's customer?
 20 A. I don't recall.
 21 Q. And similarly, anyone at
 22 Mallinckrodt during that period make any
 23 personal visits to the customers of
 24 Mallinckrodt's customers, to your knowledge?
 25 A. I don't recall.

Page 154

1 Q. You can set that aside.
2 (Mallinckrodt-Stewart Exhibit 7
3 marked for identification.)
4 QUESTIONS BY MR. GOTTO:
5 Q. We've marked as Exhibit 7 a
6 two-page document, a series of e-mails
7 bearing -- they're starting with Bates
8 MNK-T1_0003027633. They appear to be e-mails
9 that you sent in January of 2009.
10 Take a moment to look at them,
11 and tell me if you recognize them.
12 A. Okay.
13 Q. Do you recognize those e-mails?
14 A. No.
15 Q. Okay. Your January 22nd e-mail
16 is to James Champion.
17 Who was Mr. Champion?
18 A. He was my supervisor at the
19 time.
20 No, he was -- what's the date?
21 He was in charge of transportation and the
22 DCs at the time.
23 Q. Okay. So just so we're -- the
24 record's clear, your direct report during the
25 period you were customer service manager, was

Page 155

1 it Mr. Pheney?
2 A. Mr. Pheney.
3 Q. The entire time?
4 A. Yes.
5 Q. Okay.
6 A. And Mr. Champion also reported
7 to Mr. Pheney.
8 Q. Okay. So you're sending
9 Mr. Champion some information about a course
10 involving pharmaceutical diversion
11 investigation training, right?
12 A. Correct.
13 Q. And what was your reason for
14 sending that to him?
15 A. I don't recall.
16 Q. Okay. In your January 27
17 e-mail to Ms. Harper you say, "I don't know
18 how helpful this will prove to be, but I'm
19 going to approach them to see if they can
20 provide more detail."
21 Do you see that?
22 A. Uh-huh.
23 Q. Do you recall doing so?
24 A. No, I don't.
25 Q. Okay. Do you know how you

Page 156

1 became aware of the MCTC program that's
2 described in your e-mail?
3 A. We used to get flyers all the
4 time for different training and stuff, so...
5 Q. Okay. This was -- this was not
6 the result of some effort on your part to
7 identify available training in this regard?
8 A. I don't believe so.
9 Q. Okay. Do you recall if there
10 were other training courses of this type with
11 respect to diversion or suspicious order
12 monitoring that you gathered information on?
13 A. I don't recall.
14 Q. And do you know if anyone from
15 Mallinckrodt attended this course?
16 A. I don't know.
17 Q. Okay. You can set that aside.
18 Apart from the Buzzeo
19 conference, the notes that we looked at a
20 little earlier, do you know of any other
21 third-party education programs with respect
22 to diversion or suspicious order monitoring
23 that anyone at Mallinckrodt attended in the
24 2008 to 2010 time frame?
25 A. No, I don't know of any.

Page 157

1 (Mallinckrodt-Stewart Exhibit 8
2 marked for identification.)
3 QUESTIONS BY MR. GOTTO:
4 Q. Okay. We've marked as
5 Exhibit 8 a four-page document beginning at
6 Bates MNK-T1_0000457175. It appears to be a
7 customer review checklist.
8 Please take a look at that
9 exhibit. Tell me if you recognize either the
10 form of the checklist or this particular
11 checklist.
12 A. I do not recall.
13 Q. Either the form or this
14 particular --
15 A. Either. Correct.
16 Q. Okay. Do you remember if there
17 was a customer review checklist in place
18 during the time that you had customer service
19 manager responsibility?
20 A. I'm not positive.
21 Q. Do you recall having any
22 involvement in preparing the form of a
23 customer review checklist?
24 A. I may have proposed some
25 changes to a form, but I don't recall exactly

Page 158

1 to try to make it more robust.
2 Q. Okay. So Exhibit 8 is a
3 particular checklist that appears to be
4 completed with respect to a customer named
5 Paragon-Meds, right?
6 A. Yes.
7 Q. Do you know who would have had
8 responsibility for completing this checklist?
9 A. It indicates on here that Toby
10 Bane is the person that finished -- that
11 completed it.
12 Q. And who is Toby Bane?
13 A. I can only assume that he was a
14 sales rep.
15 Q. Okay. So you don't know who --
16 A. I don't remember, yeah.
17 Q. So fair to say that the
18 customer review checklist was not a document
19 that the CSRs that you supervised were
20 responsible for completing?
21 A. Correct.
22 Q. Do you know if the CSRs that
23 you supervised reviewed customer -- customer
24 review checklists?
25 A. I don't believe so.

Page 159

1 Q. Do you know who at Mallinckrodt
2 would have reviewed this checklist?
3 A. I believe it was the customer
4 data integrity group.
5 Q. During the period that you were
6 customer service manager, who was the head of
7 the customer data integrity group?
8 A. I don't remember.
9 Q. Do you remember the names of
10 any of the individuals who were involved in
11 that function?
12 A. No.
13 Q. Did you have occasion to
14 interact with the customer data integrity
15 group from time to time?
16 A. On occasion, yes.
17 Q. And for what sorts of purposes
18 would you interact with them?
19 A. There were times when, if
20 accounts were outstanding, they would turn
21 off the customer account so they couldn't
22 place any additional orders.
23 Q. Okay. Anything else?
24 A. Not that I can recall.
25 Q. In general, what was the

Page 160

1 function of the customer data integrity group
2 as you understood it?
3 A. They were the clearinghouse for
4 all of the information related to the
5 customer, and they were responsible for
6 updating all of the information.
7 Q. Okay. You can set that aside.
8 (Mallinckrodt-Stewart Exhibit 9
9 marked for identification.)
10 QUESTIONS BY MR. GOTTO:
11 Q. We've marked as Exhibit 9 a
12 two-page document beginning at Bates
13 MNK-T1_0000459916. The document's
14 encaptioned "SDIM Deliverables Worksheet."
15 Please look at that document
16 and tell me if you recognize it.
17 A. I am familiar with the intent
18 of the document but not this document that --
19 the data in the document.
20 Q. Okay. And what's your
21 familiarity with the intent of the document?
22 A. The intent of the document was
23 anytime a new program was developed by
24 information services, this was used to
25 validate that everything we had asked them to

Page 161

1 do had been completed and was tested and
2 working.
3 Q. Okay. So is this document,
4 Exhibit 9, is this something that would have
5 been prepared as part of the SOM team's
6 activities?
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: I believe so.
10 QUESTIONS BY MR. GOTTO:
11 Q. Okay. And do you know who
12 would have prepared it?
13 MR. DAVISON: Objection to
14 form.
15 THE WITNESS: No.
16 QUESTIONS BY MR. GOTTO:
17 Q. So the request title is
18 peculiar order reporting, correct?
19 A. Correct.
20 Q. And then under requirements,
21 there's a number of requirements that -- each
22 one of which has an ID number and then a
23 requirement description.
24 So am I understanding this
25 correctly that this document is basically a

Page 162

1 way for the IS department to communicate how
2 the -- how the underlying software has been
3 coded --
4 A. Correct.
5 Q. -- to achieve a certain result?
6 A. Yes.
7 Q. Okay. And the results are the
8 various requirement descriptions that are
9 listed on the document, right?
10 A. Correct.
11 Q. Okay.
12 A. But I wouldn't say that this is
13 the final document, because there are no
14 signatures or request numbers on this
15 document.
16 Q. Okay.
17 A. This could have just been an
18 iteration.
19 Q. Okay. Fair enough. You can
20 set that aside.
21 (Mallinckrodt-Stewart Exhibit
22 10 marked for identification.)
23 QUESTIONS BY MR. GOTTO:
24 Q. Exhibit 10 is a multi-page
25 document beginning at Bates MNK-T1_0000299803

Page 163

1 encaptioned "SDIM Short Form Section 3 -
2 Design."
3 Take a look at that document,
4 if you would, and tell us if you're familiar
5 either with this particular document or at
6 least the purpose of the document.
7 A. I am not familiar with the
8 purpose of this document.
9 Q. Okay. Do you know what SDIM
10 stands for?
11 A. No, I don't.
12 Q. If you turn to the next to last
13 page, or perhaps the last page, of the
14 exhibit, it has -- ends in the Bates
15 number 9809 in the bottom right.
16 A. Uh-huh.
17 Q. And do you see the box "design
18 approval" toward the bottom of the page?
19 A. Yes.
20 Q. And there's an X business
21 lead/requester, and it lists Mr. Rausch and
22 yourself, correct?
23 A. Correct.
24 Q. Does that mean for this
25 document to have become finalized, either you

Page 164

1 or Mr. Rausch would have to have signed off
2 on it?
3 MR. DAVISON: Objection to
4 form.
5 THE WITNESS: I don't know
6 that.
7 QUESTIONS BY MR. GOTTO:
8 Q. And I take it this -- this --
9 what you see in Exhibit 10 is not familiar to
10 you?
11 A. No, it's not. I would -- I
12 would have a guess at what it is for, but I
13 don't know it to be fact.
14 Q. Do you recall at any time
15 signing off on -- to give design approval
16 with respect to any, you know, program
17 design?
18 A. No.
19 Q. Above your and Mr. Rausch's
20 name on this document is a Steve Horner.
21 Do you know who he was?
22 A. Yes.
23 Q. Who was he?
24 A. He was the main programmer.
25 Q. Okay. You can set that aside.

Page 165

1 (Mallinckrodt-Stewart Exhibit
2 11 marked for identification.)
3 QUESTIONS BY MR. GOTTO:
4 Q. We've marked as Exhibit 11 a
5 two-page document beginning at Bates
6 MNK-T1_0000459923. It appears to be similar
7 to a document we looked at a little while
8 ago --
9 A. Correct.
10 Q. -- another SDIM deliverables
11 worksheet.
12 And on the second page -- there
13 are no signatures on this document. And I
14 gather from your earlier testimony, the lack
15 of those signatures would indicate that this
16 may or may not be a final document?
17 A. Correct.
18 Q. Okay. Would it be your
19 expectation that at some point a set of
20 requirements relating to peculiar order
21 reporting was ultimately signed off on by
22 appropriate people?
23 A. Yes.
24 Q. And is that something you would
25 have signed off on or someone else?

Page 166

1 A. I could have, but I don't know
2 who would have.
3 Q. Okay. Could it have been
4 Mr. Rausch?
5 A. Yes.
6 Q. Or Mr. Pheney?
7 A. Or Mr. Pheney, uh-huh.
8 Q. Okay. And you believe at some
9 point that did happen, correct?
10 A. That was the normal procedure,
11 yes.
12 Q. Okay. And where would the --
13 the final document with those signatures be
14 stored in Mallinckrodt's files; do you know?
15 A. I don't know for sure.
16 Q. Do you know what individual
17 would be responsible for maintaining those
18 materials?
19 A. I would say -- I don't know
20 what individual, but I would say it would be
21 the programming group.
22 Q. Okay. And would that be under
23 Mr. Horner's direction?
24 A. I'm not sure if he's still with
25 the company, but somebody in that capacity.

Page 167

1 Q. Okay. But at the time --
2 A. Yes.
3 Q. -- this time frame, it would
4 have been Mr. Horner?
5 A. Yes. Yes.
6 Q. Okay. Great. You can set that
7 aside.
8 (Mallinckrodt-Stewart Exhibit
9 12 marked for identification.)
10 QUESTIONS BY MR. GOTTO:
11 Q. Exhibit 12 is another --
12 similar document to Exhibit 11.
13 A. Uh-huh.
14 Q. Begins at Bates
15 MNK-T1_0000270106. And I just want to direct
16 your attention to the second page of
17 Exhibit 12. And under Requirements Approval,
18 Business Owner, it identifies you.
19 Do you see that?
20 A. Yes.
21 Q. Do you know what that phrase
22 "business owner" means in this context?
23 A. That's the individual who's
24 responsible for this process.
25 Q. Okay. And so does that

Page 168

1 indicate to you that if we were to find the
2 final approved version of these requirements,
3 it would likely contain your signature?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: I don't know.
7 Since I moved on and somebody else
8 took my place, it could be that they
9 would have signed the final document.
10 QUESTIONS BY MR. GOTTO:
11 Q. Okay. Depending on when it was
12 finalized?
13 A. Yes.
14 Q. I see. Okay. You can set that
15 aside.
16 MR. DAVISON: We've been going
17 about another hour. Is now a good
18 time or do you have -- if you're
19 almost finished with these, I'm happy
20 to do them, but...
21 MR. GOTTO: We've got plenty
22 more, so, no, this is as good a place
23 as any, so let's take our lunch break.
24 VIDEOGRAPHER: Going off the
25 record at 12:39 p.m.

Page 169

1 (Off the record at 12:39 p.m.)
2 VIDEOGRAPHER: We are back on
3 the record at 1:22 p.m.
4 (Mallinckrodt-Stewart Exhibit
5 13 marked for identification.)
6 QUESTIONS BY MR. GOTTO:
7 Q. Ms. Stewart, welcome back.
8 A. Thank you very much.
9 Q. We've marked as Exhibit 13 a
10 three-page document beginning at Bates
11 MNK-T1_0000268911. It appears to be a form
12 encaptioned "DEA Compliance Procedure."
13 Do you recognize this form?
14 A. I recognize the form. It was
15 used for all procedures, documented
16 procedures.
17 Q. So it's used for all
18 document -- procedures adopted by
19 Mallinckrodt?
20 A. Yes.
21 Q. For the purpose of complying
22 with the DEA requirement?
23 A. Any requirement.
24 Q. Okay.
25 A. Could be EPA or anything that

Page 170

1 we -- was a regulatory requirement.
2 Q. Okay. Since this one says DEA
3 compliance procedure --
4 A. Yes.
5 Q. -- obviously it's a procedure
6 to comply with the DEA requirement?
7 A. Correct.
8 Q. And there's a draft number or
9 revision number, draft 2, on it. States,
10 "Published 5/13/08."
11 Do you know what the term
12 "published" means in this context?
13 A. That this version was published
14 on that date. It's still a work in progress.
15 If it was the final version, there would be a
16 number in the upper right-hand corner and an
17 effective date in that box.
18 Q. Okay. And originator, Karen
19 Harper. Does that indicate Ms. Harper is the
20 person who, at least initially, originated
21 this procedure?
22 A. Correct.
23 Q. Okay. If you look on the
24 second page, there's some handwriting.
25 Do you recognize any of that

Page 171

1 handwriting?
2 A. No.
3 Q. Okay.
4 A. I do not.
5 Q. Okay. Do you recall at some
6 point a final controlled substance suspicious
7 order monitoring procedure being adopted?
8 A. I do not.
9 Q. Don't know one way or the
10 other?
11 A. I don't, right.
12 Q. If there were such a final
13 procedure adopted, would you expect that
14 there would be a form similar to Exhibit 13
15 but bearing a number, as you indicated, an
16 effective date?
17 A. Correct.
18 Q. And where would that be
19 maintained at Mallinckrodt, if you know?
20 A. I don't recall.
21 Q. Do you know the person who'd be
22 responsible for maintaining it in this time
23 period?
24 A. No, I -- I can't remember if it
25 was the training group that kept these,

Page 172

1 because subsequent to their publishing
2 everybody in -- who was involved had to have
3 training, and that had to be documented. So
4 I don't know if the -- if the training group
5 managed it or if there was another group that
6 did.
7 Q. Okay. In this time period, who
8 headed up the training group?
9 A. I don't recall.
10 Q. Okay. You can set that aside.
11 (Mallinckrodt-Stewart Exhibit
12 14 marked for identification.)
13 QUESTIONS BY MR. GOTTO:
14 Q. Exhibit 14 is a multi-page
15 document beginning with MNK-T1_0000459933
16 encaptioned "IS Application Service Request,
17 ASR Number," lengthy number, "Peculiar
18 Orders."
19 Do you recognize this document?
20 A. Uh-huh.
21 Q. What is it?
22 A. This is a document that was
23 filled out and -- anytime you wanted to
24 initiate assistance from the information
25 services group.

Page 173

1 Q. And so this one in particular
2 is a request pertaining to peculiar order
3 identification reporting?
4 A. Yes.
5 Q. And the ASR number, do you know
6 what that refers to?
7 A. The application service request
8 number.
9 Q. Okay. And toward the bottom of
10 the page there's an indication that --
11 "approved by business owner," and you're
12 identified.
13 Do you see that?
14 A. Correct.
15 Q. Does this indicate that you did
16 approve it or is this just indicating that
17 you would be the person who needed to approve
18 it?
19 A. That I was the person that
20 needed to approve it.
21 Q. Okay. In the top box on the
22 page, there's a request date or request
23 completion date, a system named JDE.
24 Do you know what that means?
25 A. Yes.

Page 174

1 Q. What is that?

2 A. That is the business

3 application software that we -- our order

4 entry system and billing was all facilitated

5 through JDE. I can't remember what it --

6 what the initials stood for.

7 Q. Is it JD Edwards?

8 A. Thank you. Yes.

9 Q. And then down below that

10 indicating -- there's indication, requester

11 name, with your name, so that indicates that

12 you made this particular request?

13 A. Right.

14 Q. Okay. Do you recall this

15 request?

16 A. I do.

17 Q. And what was -- what was the

18 purpose for making this request?

19 A. To develop a new program that

20 would have us in compliance with DEA requests

21 for suspicious order monitoring. And this

22 form would have actually preceded some of

23 those other forms that we looked at earlier.

24 Q. Okay. The SDIM forms that we

25 looked at?

Page 175

1 A. Yes. Yes.

2 Q. Okay. So this is actually how

3 the process would get started?

4 A. This could be the initiation of

5 the process.

6 Q. Okay. Great.

7 And so if we look under

8 description of current business need, it

9 says, "Realtime edit as CSRs enter orders

10 that identify deviations and automatically

11 place them on hold status for subsequent

12 release after order has been reviewed.

13 Calculation to determine threshold equals

14 average of, parens, previous CY plus current

15 CYTD, close parens, pieces sold times two,

16 close parens."

17 Did I read that correctly?

18 A. Yes.

19 Q. Okay. And so that indicates

20 that the formula being employed here is two

21 times the historical average, correct?

22 A. That was the -- yeah, that was

23 the first recommendation.

24 Q. Okay. And then it goes on to

25 say, "Threshold violations at customer level

Page 176

1 would be based on, one, if current order

2 greater than the calculation referenced

3 above, the order is placed on hold, and/or if

4 cumulative sum of customer's orders in the

5 prior rolling 30 days exceeds the threshold,

6 the order is placed on hold."

7 Correct?

8 A. Uh-huh.

9 Q. And then "exclusions would be

10 based on class of trade, specific customers,

11 parens, parent and all children, close

12 parens, would be excluded from review

13 process, parens, identified by John Adams,

14 close parens."

15 What does that mean, that the

16 parents and all children -- well, that

17 specific customers would be excluded through

18 this review process?

19 A. In the case of McKesson, there

20 was a corporate account for McKesson, and

21 then each of their DCs would have been a

22 child.

23 Q. Okay. And why would those have

24 been excluded from the review process?

25 A. I do not know. I don't recall.

Page 177

1 Q. Okay. It goes on to says,

2 "Interim requirement would be to run report

3 RPT784 R1 twice daily, once at 11 a.m.

4 Eastern Standard Time and against" --

5 I assume that means again?

6 A. Again.

7 Q. -- "at 3 p.m. Eastern Standard

8 Time for distribution to Cathy Stewart,

9 Brenda Rehkop, John Adams, Mike Gunning and

10 Eileen Spaulding."

11 Who was Brenda Rehkop?

12 A. Brenda Rehkop was one of the

13 lead customer service reps on the dosage side

14 of the business.

15 Q. Okay.

16 A. So if I was out or in a meeting

17 or something and the report needed to run and

18 be evaluated, she would have done it.

19 Q. Okay. And who was Mike

20 Gunning?

21 A. Mike Gunning was the vice

22 president, and he was over all of the

23 methadone business.

24 Q. Okay. And under business

25 benefit it says, "Places us in compliance

Page 178

1 with DEA regulations requiring auditing of
 2 customer orders to identify those which might
 3 be deemed suspicious so they can be
 4 circumvented from being placed in
 5 transportation."
 6 Did you personally draft the
 7 text that's under the description in the
 8 business benefit sections?
 9 A. I believe so.
 10 Q. Was this something you did at
 11 the request of the SOM team?
 12 A. I don't recall.
 13 Q. So it's a request that you made
 14 in August of '08.
 15 Would that indicate that the
 16 SOM team had been formed by this time and had
 17 begun to work?
 18 A. Possibly.
 19 Q. Do you recall placing any
 20 follow-up requests of the sort indicated in
 21 Exhibit 14 on the subject matter?
 22 A. I don't recall that follow-up
 23 formal requests were required. The IT team
 24 participated in the meetings, so as questions
 25 and issues and revisions came up, they just

Page 179

1 made notes. And that's why we had these
 2 documents, to make sure all of that stuff was
 3 captured.
 4 Q. Okay. Great. You can put that
 5 aside.
 6 (Mallinckrodt-Stewart Exhibit
 7 15 marked for identification.)
 8 QUESTIONS BY MR. GOTTO:
 9 Q. We've marked as Exhibit 15
 10 another DEA compliance procedure draft, this
 11 one beginning with Bates MNK-T1_0000420019.
 12 This one indicates revision number or draft
 13 4, published 7/15 of '08.
 14 This draft, if you look through
 15 it, includes some additional material beyond
 16 what was in the prior DEA compliance
 17 procedure that we looked at with respect to,
 18 for example, the customer service
 19 representative responsibilities and the IS
 20 department responsibilities.
 21 Do you see that?
 22 A. Yes.
 23 Q. I'd like you to look at the
 24 second page of Exhibit 15 under customer
 25 service representative responsibilities --

Page 180

1 A. Uh-huh.
 2 Q. -- and I'd like to just have
 3 you confirm if these responsibilities were,
 4 in fact, included in the customer service
 5 representative responsibilities under the
 6 suspicious order monitoring program as
 7 ultimately adopted.
 8 MR. DAVISON: Objection.
 9 QUESTIONS BY MR. GOTTO:
 10 Q. And if you would just -- you
 11 can just read 1 to 6 to yourself.
 12 A. Okay. Okay.
 13 Q. Okay. So there were six
 14 numbered items under customer service
 15 representative responsibilities.
 16 Do you recall if all six of
 17 these responsibilities were included in the
 18 final SOM procedure that was adopted?
 19 A. I don't know if they were or
 20 not.
 21 Q. Okay. Do you recall any
 22 responsibilities of the customer service
 23 representatives that you supervised with
 24 respect to suspicious order monitoring beyond
 25 those that are described in Items 1

Page 181

1 through 6?
 2 A. No.
 3 Q. Okay. Now under Item 4, for
 4 C-I and C-II controlled substance orders, do
 5 you know what C-I and C-II mean?
 6 A. Yes.
 7 Q. What's that?
 8 A. That's the class of drug as
 9 classified by the DEA.
 10 Q. Okay. So for those -- for C-I
 11 and C-II controlled substances, under A,
 12 "verify customer has provided a DEA 222
 13 form," we've discussed that already today,
 14 correct?
 15 A. Right.
 16 Q. "B, obtain a certificate of
 17 available procurement quota from customers
 18 using a manufacturing registration DEA 222
 19 form."
 20 And I think you've already
 21 testified with respect to the quota element
 22 as it applied --
 23 A. Yes.
 24 Q. -- to a manufacturer.
 25 And that would be someone

Page 182

1 purchasing API, correct?
2 A. API, correct.
3 Q. Okay. And then under C,
4 "obtain a statement of intended use from
5 customers using a research compounding
6 pharmacy or analytical lab registration, DEA
7 222 form."
8 And were there such customers?
9 A. Yes.
10 Q. Okay. And then under C there's
11 I, "forward the statement of intended use to
12 DEA compliance."
13 So with respect to customers
14 who were neither -- whose registration with
15 DEA was neither a manufacturing registration
16 nor a research compounding pharmacy or
17 analytical lab registration, is it accurate
18 that as to C-I and C-II controlled
19 substances, the customer service
20 representative was responsible to verify that
21 the customer had provided a DEA 222 form but
22 did not otherwise have responsibility for any
23 other verification of the type described
24 under Item 4 on this page?
25 MR. DAVISON: Objection to

Page 183

1 form.
2 THE WITNESS: Correct.
3 QUESTIONS BY MR. GOTTO:
4 Q. Okay. Then below customer
5 service representative, there's a heading
6 Customer Service Manager, and that's the role
7 you played first as to dosage and then later
8 as to API, correct?
9 A. Correct.
10 Q. And the responsibilities there
11 in number 1, "review the IS system generated
12 peculiar order report which lists orders that
13 meet the criteria established in this
14 procedure" --
15 And that's something you did,
16 correct?
17 A. Correct.
18 Q. -- "and annotate the report
19 with applicable explanation that authorizes
20 shipment of peculiar orders that deviates
21 from normal order pattern, size, frequency,
22 such as trade show sales," et cetera.
23 Do you recall so annotating
24 peculiar order reports?
25 A. I believe so.

Page 184

1 Q. And would that have been --
2 what form would that annotation have taken?
3 A. Just a note on the actual
4 report that was generated by IS and then
5 filed away.
6 Q. Okay. Would that be a
7 handwritten note?
8 A. Yes.
9 Q. Okay. And then file -- that
10 would then be filed away where?
11 A. I personally kept a file in my
12 desk for all of the suspicious order reports
13 that were generated.
14 Q. Okay. And so that's a file
15 that existed when you left --
16 A. Yes.
17 Q. -- the customer service manager
18 position?
19 A. Correct.
20 Q. Okay. Heading B, manually
21 release orders in the order entry system that
22 are authorized to ship.
23 That's something you did?
24 A. Yes.
25 Q. Okay. And that could have been

Page 185

1 based on your own review of the peculiar
2 orders or perhaps Karen Harper --
3 A. Or Karen's --
4 Q. -- or someone else's review?
5 A. Yes.
6 Q. Okay. Other than yourself or
7 Karen Harper, is there anyone else you can
8 recall authorizing the shipment of an order
9 that had been identified as peculiar?
10 A. The only other person that
11 would have would have been Bill Ratliff. He
12 was the director of security.
13 Q. Okay. Do you recall any
14 particular circumstances where Mr. Ratliff
15 gave that authorization?
16 A. No.
17 Q. Okay. "Item C, for orders that
18 have no application explanation for deviation
19 from normal order pattern, size, frequency,
20 the order will remain on hold pending further
21 investigation by the business group and
22 security/DEA compliance."
23 Do you see that?
24 A. Yes.
25 Q. Do you recall there being any

Page 186

1 such orders during the period when you were
2 customer service manager?
3 A. I recall there were times I
4 felt that I didn't have enough information
5 available to me to make the decision, and I
6 would kick it up to Karen and Bill for
7 review.
8 Q. Okay. And on each of those
9 occasions, ultimately, was the order
10 released?
11 A. I don't know that they were all
12 released.
13 Q. Okay. Do you recall any that
14 ultimately were not fulfilled because of the
15 operation of the suspicious order monitoring
16 program?
17 A. I can't recall off the top of
18 my head.
19 Q. Item 2 says, "Maintains the do
20 not ship list on the share drive by updating
21 for any customer for which shipment has been
22 canceled based on suspicious order criteria."
23 What was the do not ship list?
24 A. Originally it was just a piece
25 of paper that customer service reps wrote

Page 187

1 account numbers on if they should not be
2 shipped to because they were questionable
3 practices.
4 Later we decided that it wasn't
5 prudent to depend on a handwritten list, so
6 we got with the customer data integrity group
7 and set up a table so that if a customer's
8 number was entered in the system, the table
9 would kick them out as not being allowed to
10 enter an order.
11 Q. Okay. And who had authority to
12 place a customer on the do not ship list?
13 A. It could have been any number
14 of people. It could have been DEA
15 compliance. It could have been finance. It
16 wasn't just for DEA things. It could have
17 been they're not paying their bills, so we're
18 not going to ship to them anymore until we
19 get it resolved.
20 Q. Okay.
21 A. So it served a host of
22 purposes.
23 Q. Okay. Well, with respect to
24 DEA concerns --
25 A. Yes.

Page 188

1 Q. -- who would have had authority
2 to place customers on the do not ship list?
3 A. I would say Eileen Spaulding in
4 Hobart, and Karen and possibly myself. I
5 don't remember that I actually did, but...
6 Q. Okay. How about Jim Rausch?
7 A. Yes, Jim could have as well.
8 Q. Okay. Do you remember any
9 occasions when -- I mean, you just testified
10 that you don't recall personally ever doing
11 so, correct?
12 A. Right.
13 Q. Do you remember occasions where
14 Mr. Rausch did that?
15 A. I don't know.
16 Q. And how about Ms. Spalding?
17 A. I don't know -- I do recall
18 that Eileen had called and talked about put
19 this guy on the do not ship list, so I would
20 say, yes, she did, but I don't know what --
21 what the -- I don't recall what the
22 circumstances were.
23 Q. Or who the customer was?
24 A. Or who the customer was,
25 correct.

Page 189

1 Q. How about Ms. Harper, do you
2 recall her ever putting anyone on the do not
3 ship list for DEA regulatory reasons?
4 A. No, I don't recall.
5 Q. And in the -- the occasion
6 involving Ms. Spalding that you recall, was
7 that a single occasion?
8 A. Yes.
9 Q. Okay.
10 A. But not limited to. She could
11 have done more than one, but I do recall one.
12 Q. Okay. In terms what you
13 actually recall today --
14 A. Yeah.
15 Q. -- it's one?
16 A. Yes.
17 Q. And whether it's more than one
18 or not, you don't know as you sit here today?
19 A. Right.
20 Q. Okay. You can put that aside.
21 (Mallinckrodt-Stewart Exhibit
22 16 marked for identification.)
23 QUESTIONS BY MR. GOTTO:
24 Q. Exhibit 16 is a one-page e-mail
25 from Karen Harper bearing Bates

Page 190

1 MNK-T1_0000301990, and it's an e-mail
2 addressed to Bill Ratliff, Michael Pheney,
3 Jim Rausch and yourself inviting you to a
4 meeting on April 1 on the subject of
5 suspicious order monitoring conference call
6 with DEA consultant.
7 Do you see that?
8 A. I do.
9 Q. Do you recall participating in
10 that meeting?
11 A. I do not.
12 Q. Do you know who the DEA
13 consultant was?
14 A. I do not.
15 Q. Do you know what the Hazelwood
16 conference room is?
17 A. Yes.
18 Q. And where is that?
19 A. It's -- Hazelwood had three
20 buildings at the main campus, the corporate
21 offices, so that's what we called the
22 Hazelwood building, campus.
23 Q. Okay. You can set that aside.
24 Well, before you set that
25 aside, it's -- the invitation is for a

Page 191

1 meeting on April 1 --
2 A. Uh-huh.
3 Q. -- of 2008.
4 Do you know if the -- if the
5 SOM team had been formed at this point?
6 A. I don't recall.
7 Q. Okay. You can set that aside.
8 (Mallinckrodt-Stewart Exhibit
9 17 marked for identification.)
10 QUESTIONS BY MR. GOTTO:
11 Q. Exhibit 17 are a thread of
12 e-mails from March of 2008 -- well, actually,
13 begin in January -- two pages beginning at
14 MNK-T1_0000419874.
15 Direct your attention to the
16 March 12 e-mail from Karen Harper to you, the
17 second e-mail on the page.
18 It says, "Since you -- since
19 you will {sic} are included in the conference
20 call with DEA consultants in early April, the
21 attached information is provided as
22 background for you. It was previously sent
23 to Michael Pheney and Jim Rausch."
24 Now, Ms. Harper's e-mail refers
25 to a conference call with plural DEA

Page 192

1 consultants.
2 Do you recall ever
3 participating in a conference call with
4 multiple DEA consultants?
5 A. I do not.
6 Q. Okay. So do you have any idea
7 what information was provided to you along
8 with Ms. Harper's March 12th e-mail?
9 A. No.
10 Q. Okay. You can set that aside.
11 (Mallinckrodt-Stewart Exhibit
12 18 marked for identification.)
13 QUESTIONS BY MR. GOTTO:
14 Q. Exhibit 18 is a two-page
15 document beginning at Bates
16 MNK-T1_0000391444. It's two e-mails from
17 April 10 of 2008.
18 Take a look at those e-mails,
19 if you would, and tell me if you recognize
20 either one of them.
21 A. No.
22 Q. Okay. If you look at Karen
23 Harper's April 10 e-mail on the bottom part
24 of the page, under additional items for
25 consideration, she says, "Cathy and Michael,

Page 193

1 should there be a separate suspicious order
2 checklist for dosage versus bulk?"
3 Do you see that?
4 A. Yes, I do.
5 Q. Do you recall responding to
6 that -- that inquiry?
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: Based on the
10 reports that were ultimately
11 generated, I assume that we did agree
12 that there should be two separate
13 reports.
14 QUESTIONS BY MR. GOTTO:
15 Q. And does that mean there would
16 be two separate checklists for dosage and
17 bulk?
18 A. Yes.
19 Q. And do you recall what the
20 differences were between the two?
21 A. Bulk customers buy in large
22 quantities, in kilograms, where dosage
23 customers buy in tiny quantities of API in
24 comparison.
25 Q. Okay. And so apart from the

Page 194

1 quantity of the orders at issue, were there
2 other differences between the two checklists
3 you can recall?
4 A. I can't recall.
5 Q. Okay. You can set that aside.
6 (Mallinckrodt-Stewart Exhibit
7 19 marked for identification.)
8 QUESTIONS BY MR. GOTTO:
9 Q. Exhibit 19 is a two-page
10 document beginning at Bates
11 MNK-T1_0000304544, a series of e-mails
12 between yourself and Ms. Harper, with various
13 other parties copied, on the topic of a
14 suspicious ordering flow chart.
15 Take a moment to look at those
16 e-mails and the attached flow chart, and tell
17 me if you recognize either the e-mails or the
18 flow chart.
19 A. Okay.
20 Q. Do you recognize either of
21 those materials?
22 A. I mean, I'm sure I wrote it,
23 but, no, I don't recall writing it.
24 Q. Okay. So it appears that -- I
25 mean, the e-mail on the bottom of the first

Page 195

1 page is an e-mail from you to Ms. Harper --
2 A. Correct.
3 Q. -- and you're communicating
4 some questions you've got regarding the flow
5 chart, correct?
6 A. Correct.
7 Q. And if we look at the flow
8 chart, there's some handwriting on there.
9 Is that your handwriting?
10 A. No.
11 Q. Okay. Do you know whose it is?
12 A. I'm not positive.
13 Q. Okay. So the handwritten
14 changes to the flow chart itself have some --
15 have some additional boxes under obtained
16 statement of use, correct?
17 A. Correct.
18 Q. And there's some asterisks by
19 them that seems to indicate that the source
20 of those additional boxes is an e-mail that
21 you had sent?
22 MR. DAVISON: Objection to
23 form.
24 THE WITNESS: I guess.
25

Page 196

1 QUESTIONS BY MR. GOTTO:
2 Q. Do you recall making the
3 suggestions that are indicated on the flow
4 chart on the second page of Exhibit 18 -- 19,
5 rather?
6 A. No.
7 Q. Okay. On the flow chart,
8 there's a box that states, "Obtained
9 statement of use."
10 Do you see that?
11 A. Yes.
12 Q. What is a statement of use as
13 used here?
14 A. For some of our customers that
15 were doing research or analytics, we required
16 an explanation on a form what they were --
17 what their intent was in using the product.
18 Q. Okay. And as the flow chart
19 had originally been prepared before the
20 handwritten changes, once the statement of
21 use was obtained, the order would be
22 processed, correct?
23 MR. DAVISON: Objection to
24 form.
25 THE WITNESS: Depending on the

Page 197

1 answer, yes.
2 QUESTIONS BY MR. GOTTO:
3 Q. And with the handwritten
4 changes to the flow chart, the statement of
5 use would be submitted -- or strike that.
6 The security director or DEA
7 COMP manager --
8 A. Compliance manager.
9 Q. Compliance manager.
10 -- would be notified?
11 A. Yes.
12 Q. And that person would make a
13 determination as to the appropriateness of
14 the statement of use, correct?
15 A. Correct. Yes.
16 MR. DAVISON: Objection to
17 form.
18 (Mallinckrodt-Stewart Exhibit
19 20 marked for identification.)
20 QUESTIONS BY MR. GOTTO:
21 Q. Okay. Exhibit 20 is a
22 single-page new customer account setup flow
23 chart bearing Bates MNK-T1_0000420013.
24 Do you recognize this document?
25 A. No.

Page 198

1 Q. Okay. Any idea who might have
2 prepared it?
3 MR. DAVISON: Objection to
4 form.
5 THE WITNESS: No. It would be
6 speculation.
7 QUESTIONS BY MR. GOTTO:
8 Q. Okay. The top center of the
9 page in the top box indicates "field sales
10 completes customer checklist."
11 Do you see that?
12 A. Yes.
13 Q. And we looked at a customer
14 checklist earlier today, you recall?
15 A. Correct.
16 Q. And I think you testified you
17 didn't know at that time who would have been
18 responsible for preparing it?
19 A. Right.
20 Q. Does this refresh your
21 recollection as to who prepared the customer
22 checklist?
23 A. No.
24 Q. Okay. You can put that aside.
25 (Mallinckrodt-Stewart Exhibit

Page 199

1 21 marked for identification.)
2 QUESTIONS BY MR. GOTTO:
3 Q. Exhibit 21 is a two-page e-mail
4 beginning at Bates MNK-T1_0000274111. It
5 appears to be an e-mail from you to a number
6 of individuals dated March -- I'm sorry,
7 May 14, 2008.
8 A. Correct.
9 Q. Would you take a look at that
10 e-mail and tell me if you can recall having
11 sent it?
12 A. Okay.
13 Q. Do you recall sending this
14 e-mail?
15 A. Yes.
16 Q. Okay. Now, you -- persons to
17 whom it's addressed, there are a few names
18 here we haven't talked about yet today.
19 Vince J. Kaiman, who was that?
20 A. Vince was one of the vice
21 presidents. I believe he was over the
22 branded dosage products.
23 Q. Okay. And Mike Neely, who was
24 that?
25 A. Mike Neely worked with Mike

Page 200

1 Gunning in the methadone business.
2 Q. Okay. How about Marco Polizzi?
3 A. Marco Polizzi was one of the
4 sales bosses. The sales reps reported up
5 through Marco.
6 Q. Okay.
7 A. So he was like a business
8 owner.
9 Q. Okay. How about Jeff Burd?
10 A. The same as Marco, a business
11 owner.
12 Q. And Sue Werder?
13 A. Sue Werder, if memory serves me
14 correctly, she was over the customer data
15 integrity group, but I can't swear to that.
16 Q. Okay. And one of the cc's is a
17 JoAnne Levy?
18 A. JoAnne Levy was my vice
19 president. She was over the logistics
20 organization.
21 Q. Okay. All right. And so in
22 your e-mail you say, "I wanted to advise all
23 of you that we're working with security and
24 the DEA compliance group, Bill Ratliff and
25 Karen Harper, to develop procedures to ensure

Page 201

1 we maintain compliance with the DEA
2 requirement that we report any suspicious
3 order quantities and/or patterns to them. In
4 light of the recent developments with
5 McKesson, a good deal of focus is being
6 placed on this project."
7 Correct?
8 A. Correct.
9 Q. And so what were the recent
10 developments with McKesson that you're
11 referring to here?
12 A. I don't recall specifically off
13 the top of my head, other than there were
14 some anomalies, and I believe they were
15 reprimanded, possibly suspended, by DEA.
16 Q. Okay. So is that what
17 triggered the development of the SOM
18 procedures, concerns arising out of the
19 recent developments with McKesson?
20 MR. DAVISON: Objection to
21 form.
22 THE WITNESS: No. Our initial
23 dedication to the suspicious order
24 monitoring program was a result of
25 having attended that meeting and being

Page 202

1 advised by DEA that perhaps companies
 2 were doing too little, too late, and
 3 it needed -- they needed more robust
 4 systems, so we started implementing
 5 that.
 6 This was -- what happened with
 7 McKesson was it just added fuel to the
 8 fire for why we needed to pay
 9 attention, because McKesson was a big
 10 customer of ours.
 11 QUESTIONS BY MR. GOTTO:
 12 Q. Okay. And when you say "that
 13 meeting," it's the Washington, DC
 14 conference --
 15 A. Correct.
 16 Q. -- in late October?
 17 A. Yes, the Buzzeo, uh-huh.
 18 Q. All right. You go on to say,
 19 "Briefly, if an order is deemed peculiar by a
 20 customer service rep based on a set of
 21 guidelines currently being developed, it will
 22 be placed on hold and the DEA compliance
 23 group, Bill Ratliff and Karen Harper, will be
 24 advised. DEA compliance will then conduct a
 25 more in-depth investigation and determine if

Page 203

1 the situation warrants notification to the
 2 DEA. If the order is deemed appropriate,
 3 customer service will be notified and the
 4 order will be released from hold status for
 5 shipment. If the order -- if the outcome of
 6 the investigation supports that the order is
 7 in fact suspicious, it will not be shipped
 8 and the local DEA office will be notified."
 9 Did I read that correctly?
 10 A. Yes.
 11 Q. And in fact, is that the
 12 procedure that was adopted?
 13 A. I don't know if that was the
 14 final procedure that was adopted. It was
 15 what was recommended at this time.
 16 Q. Okay. And down below, three
 17 paragraphs, the paragraph that begins with
 18 "As these respected."
 19 Do you see it?
 20 A. Uh-huh.
 21 Q. That paragraph concludes with
 22 the statement, "At first pass, the formula
 23 might look like this, colon," and then you
 24 list a number of items that are under
 25 consideration for inclusion in the formula,

Page 204

1 correct?
 2 A. Correct.
 3 Q. First of those items is
 4 "customers will be separated into their
 5 respective class of business: distributors,
 6 wholesalers, clinic, hospital, retail, et
 7 cetera."
 8 A. Uh-huh.
 9 Q. Was that, in fact, part of the
 10 final SOM procedure?
 11 MR. DAVISON: Objection to
 12 form.
 13 THE WITNESS: I don't know.
 14 QUESTIONS BY MR. GOTTO:
 15 Q. Are there other classes of
 16 business, other than the ones you
 17 specifically identify in that parenthetical?
 18 A. I believe there were.
 19 Q. What can you recall?
 20 A. We had researchers, and
 21 compounding laboratories, compounding
 22 pharmacies, were a couple other classes. I
 23 don't recall if there were any others.
 24 Q. Okay. Next bullet item is,
 25 "add purchase quantities by product, all oxy

Page 205

1 products and again by individual SKUs, for
 2 the last 12 months for all customers within
 3 the same class of business for any controlled
 4 substances."
 5 Correct?
 6 A. Uh-huh.
 7 Q. What does it mean when it says,
 8 "All oxy products and again by individual
 9 SKUs"?
 10 A. We had multiple SKUs of oxy
 11 based on the quantity of API that was in each
 12 pill and the quantity of acetaminophen that
 13 was in it as well.
 14 And then counts -- so we had
 15 5/325s, but they came in 50 counts, hundred
 16 counts, 250-count bottles. So you wanted to
 17 normalize all of that data so you're not
 18 counting -- you're not calling ten 500-count
 19 bottles as, oh, that's no big deal because
 20 it's only ten bottles compared to 500, maybe,
 21 100-count bottles. So we tried to normalize
 22 all the data.
 23 Q. Okay. And I understand the
 24 normalization you just described. I'm
 25 wondering when it says "all oxy product and

Page 206

1 again by individual SKUs," what the "and
2 again by individual SKUs" means.
3 A. The SKUs were the quantity per
4 bottle and the dose. So, oh, there were so
5 many different oxy products, I can't recall
6 exactly what the intent of that was.
7 Q. Okay. The next bullet item,
8 "Add customer months for every record used in
9 the above total."
10 Next bullet item, "Divide total
11 quantity purchases by the total customer
12 months."
13 Next bullet item, "Then
14 multiply by the factor below to give the
15 maximum amount that the customer can order
16 per month before showing up on the suspicious
17 order report."
18 And the factor is 2 for C-II
19 controlled substances and 4 for C-III, IV and
20 V controlled substances, right?
21 A. Correct.
22 Q. And we talked about the 2 X
23 factor in the context of some other materials
24 we've looked at here today.
25 Do you recall the 4 X factor

Page 207

1 ever being adopted for the Schedule III, IV
2 or V controlled substances?
3 A. I don't recall.
4 Q. Okay. Do you remember what
5 your basis was for referring to at least a
6 potential 4 X factor for those materials?
7 A. Because their propensity for
8 abuse was less than a C-II product.
9 Q. Okay. Was there -- had there
10 been discussion among the SOM group of a 4 X
11 factor for Schedule III, IV and V product?
12 A. Based on this e-mail I would
13 say there was, but I can't swear to that.
14 Q. Okay. You don't independently
15 recollect that today?
16 A. Right.
17 Q. Okay. On the second page of
18 the exhibit, the first full paragraph says,
19 "In addition to order quantities by product,
20 we hope to also develop criteria for orders
21 that deviate from normal ordering patterns
22 and from usual order frequency, parens, not
23 yet sure how to capture this, hope to
24 identify an algorithm that will support
25 parsing through the data to identify

Page 208

1 patterns, frequency, et cetera, close
2 parens."
3 So do you recall if ultimately
4 there were means established by which to
5 identify orders as deviating from normal
6 order patterns or from usual order frequency?
7 MR. DAVISON: Objection. Form.
8 THE WITNESS: I am not sure.
9 QUESTIONS BY MR. GOTTO:
10 Q. Do you have any recollection at
11 all at what some of the metrics were that
12 you -- or that the team considered using in
13 that regard?
14 MR. DAVISON: Objection to
15 form.
16 THE WITNESS: I don't recall.
17 QUESTIONS BY MR. GOTTO:
18 Q. The next paragraph says, "The
19 group is working on other indicators that
20 might be used in evaluating whether or not a
21 customer should be reported as peculiar. The
22 sales force will play a key role in this
23 process by verifying the customer's physical
24 site and operations ring true with the type
25 of business they purport to run."

Page 209

1 Correct?
2 A. Correct.
3 Q. And in fact, in the SOM as
4 ultimately adopted, did the sales force have
5 a role to play -- have the verification role
6 to play that's described in this paragraph?
7 A. I don't know.
8 Q. Now, in the notes that you took
9 from the conference in Washington, DC, you
10 noted that there was some -- at least concern
11 expressed using the sales force for this type
12 of function, correct?
13 A. Uh-huh, correct.
14 Q. Was there a reason that
15 consideration was given to using the
16 Mallinckrodt sales force for this role
17 despite the concerns that you noted in those
18 notes?
19 MR. DAVISON: Objection. Form.
20 THE WITNESS: They were the
21 feet on the ground, and they were
22 familiar with the physical location,
23 whether or not the customer had vaults
24 or not. That was things the customer
25 service reps didn't have visibility

Page 210

1 to. So we had to depend on them to --
2 and the DEA compliance group as well
3 on parsing through the -- you know, do
4 they appear legitimate. And if they
5 had -- ultimately if they had a DEA
6 registration number, who are we to,
7 you know, say that they're not
8 legitimate, unless there was something
9 suspicious that we saw, you know, like
10 they don't have a vault for C-II's or
11 whatever.
12 QUESTIONS BY MR. GOTTO:
13 Q. But in terms of that sort of
14 physical evaluation of their facilities, that
15 was something you relied on the sales
16 force --
17 A. Yes.
18 Q. -- to do?
19 A. Yes.
20 Q. And do you recall there being
21 any situations in which a customer was
22 declined -- a customer that had a DEA
23 registration was declined based upon reports
24 from -- a report or multiple reports from the
25 sales force with respect to the results of a

Page 211

1 site visit or other review of their physical
2 facility?
3 A. I do recall there were a couple
4 instances where Mallinckrodt sent a team to
5 audit the customer, to validate the
6 information that we were getting, but I don't
7 recall what the disposition of those audits
8 were.
9 Q. Okay. And that would have been
10 an audit of a customer that had already been
11 accepted, correct?
12 A. Yes.
13 Q. Was Sunrise one of those?
14 A. I don't recall.
15 Q. Okay. The last paragraph, you
16 indicate the process is in a preliminary
17 stage. Given that, was there a reason you
18 sent this -- this e-mail to the group that's
19 identified on here at the time that you did?
20 A. To -- just to let them know
21 what was coming down the pipeline so they
22 could let the sales reps know that if a
23 customer calls and complains that they had an
24 order put on hold, this is why. So we didn't
25 blind side anybody.

Page 212

1 Q. Okay. But at this point, at
2 least as of May 14th of 2008, the system was
3 not yet sufficiently mature to where --
4 A. No.
5 Q. -- a customer would have been
6 put on hold?
7 A. No, correct. Unless a customer
8 service rep thought there was something
9 suspicious about the order, like a large
10 increase in volume or something like that.
11 Q. But that would have been no
12 different from prior practice, right?
13 A. Right.
14 Q. Okay. You can set that aside.
15 (Mallinckrodt-Stewart Exhibit
16 22 marked for identification.)
17 QUESTIONS BY MR. GOTTO:
18 Q. Exhibit 22 is a single-page
19 series of e-mails bearing Bates
20 MNK-T1_0000391443.
21 And you're an addressee on the
22 second -- on the earlier e-mail in this
23 string.
24 A. Uh-huh.
25 Q. My first question for you is

Page 213

1 whether you recognize any of the handwriting
2 on this page.
3 A. I think I do.
4 Q. Okay. What do you think you
5 recognize?
6 A. I think this is the handwriting
7 of Karen Harper.
8 Q. Okay. All of it?
9 A. Yes.
10 Q. Okay. So toward the top of the
11 page, the handwriting up top, 6/3/08, appears
12 to say "algorithm subcommittee sales data for
13 six customers in each category will be
14 queried by Cathy Stewart."
15 Is that --
16 A. Yeah.
17 Q. Is that your reading of it as
18 well?
19 MR. DAVISON: Objection.
20 THE WITNESS: Yeah.
21 QUESTIONS BY MR. GOTTO:
22 Q. And do you know what's being
23 referred to there?
24 MR. DAVISON: Objection to
25 form.

Page 214

1 THE WITNESS: I don't recall.
2 QUESTIONS BY MR. GOTTO:
3 Q. Do you know if the algorithm
4 subcommittee is the same committee as the SOM
5 team?
6 A. I don't know for sure.
7 Q. Do you recall there being a
8 different algorithm subcommittee?
9 A. No.
10 Q. Okay. Down toward the bottom
11 of the page, about two-thirds of the way
12 down, here's handwritten notes, "growth rate
13 data available by product: oxycodone
14 15-milligram plus 30-milligram rapid
15 increase," and to the right, "competitive
16 recall, 5-milligram oxy, slow growth."
17 Do you see that?
18 A. Yes.
19 Q. Do you know what growth rate
20 data was available by product that's being
21 referred to here?
22 MR. DAVISON: Objection to
23 form.
24 THE WITNESS: No, I don't.
25

Page 215

1 QUESTIONS BY MR. GOTTO:
2 Q. And then down below that
3 there's language "algorithms vary by customer
4 category."
5 Do you see that?
6 A. Yes.
7 Q. And goes on to say "generic,"
8 and apparently AT --
9 A. AT is addiction therapy.
10 Q. Okay. Then international?
11 A. Uh-huh.
12 Q. Brand outsourcing?
13 A. Uh-huh.
14 Q. Et cetera.
15 Do you recall if there were
16 different algorithms ultimately adopted by
17 different customer category?
18 A. I don't recall.
19 Q. Okay. You can set that aside.
20 (Mallinckrodt-Stewart Exhibit
21 23 marked for identification.)
22 QUESTIONS BY MR. GOTTO:
23 Q. Exhibit 23 is a single-page
24 e-mail bearing Bates MNK-T1_000002023.
25 Appears to be an invitation you sent to Jim

Page 216

1 Rausch and Edward Wright for a June 26, 2008
2 meeting to discuss proposed modification to
3 Hobart's dosage suspicious order report.
4 Do you recall sending this
5 invitation?
6 A. I don't recall it.
7 Q. Okay. Who was Edward Wright?
8 A. Edward Wright was a member of
9 the programming team.
10 Q. So was he part of the SOM team?
11 A. I don't believe so. I don't
12 think Ed wrote new code, but he revised
13 existing reports that were generated.
14 Q. Okay. And when you say
15 "discuss proposed modification to Hobart's
16 dosage suspicious orders report," what is
17 that report that you're referring to?
18 A. I don't remember.
19 Q. Was it a -- something different
20 from the peculiar order report that the --
21 that the team --
22 A. Team was developing? This --
23 MR. DAVISON: Objection to
24 form.
25 THE WITNESS: Sorry. Thank

Page 217

1 you.
2 MR. DAVISON: Let him finish
3 his questions.
4 THE WITNESS: I'm -- this is
5 supposition on my part, but I believe
6 that this report would have been the
7 monthly dosage report that Karen
8 Harper would have been sending to DEA
9 in New York, as Jim was sending to
10 Pete Kleissle here in St. Louis, and
11 we were trying -- you know, if it's
12 suspicious, don't ship. And so we
13 were trying to get them to be
14 generated more expeditiously so we
15 could do something about it if there
16 was something suspicious.
17 QUESTIONS BY MR. GOTTO:
18 Q. Okay. All right. You can set
19 that aside.
20 (Mallinckrodt-Stewart Exhibit
21 24 marked for identification.)
22 QUESTIONS BY MR. GOTTO:
23 Q. Exhibit 24 is a single-page
24 e-mail from Mr. Rausch to yourself and
25 Ms. Harper and Steve Horner bearing Bates

Page 218

1 MNK-T1_0000305967, and appears to be an
2 invitation to a meeting on suspicious order
3 monitoring requirements.
4 And Mr. Rausch says, "Karen,
5 Cathy, I would like to finalize if possible
6 our threshold requirement for JDE. We have
7 discussed average of previous CY plus current
8 CYTD times two as current threshold."
9 Do you see that?
10 A. Uh-huh.
11 Q. Do you know what JDE is?
12 A. Yes, it's our order entry
13 system.
14 Q. Okay. And I know we've spoken
15 earlier here today regarding the 2 X factor
16 compared to the averages.
17 Does this refresh your
18 recollection as to whether a 2 X factor was
19 ultimately adopted as part of the SOM
20 monitoring?
21 A. No.
22 Q. The last sentence on -- or
23 paragraph, rather, on Exhibit 24, Mr. Rausch
24 says, "We need to come up with a new customer
25 threshold level. What formula do we use for

Page 219

1 setting this threshold up? Give it some
2 thought prior to the meeting."
3 Do you recall the formula that
4 was ultimately -- well, do you recall if
5 there was a formula ultimately adopted for
6 use with new customers?
7 A. I don't recall.
8 Q. Okay. Do you recall any
9 suggestions that anyone made with respect to
10 what the components of such a formula would
11 include?
12 A. I don't know.
13 (Mallinckrodt-Stewart Exhibit
14 25 marked for identification.)
15 QUESTIONS BY MR. GOTTO:
16 Q. Okay. Exhibit 25 is a
17 multi-page PowerPoint presentation that was
18 produced in native at MNK-T1_0002906584.
19 Would you take a look at that
20 exhibit, please, and tell me if you recognize
21 this or recall the event to which it
22 pertains?
23 A. I do recall this Kaizen event.
24 Q. Okay. What is a Kaizen event?
25 A. It's when you try to refine

Page 220

1 your process, take the waste out of it to
2 make it more efficient.
3 Q. Okay. And you're included
4 among the team members who participated in
5 this event, correct?
6 A. Correct.
7 Q. And so on the -- and these
8 pages, I don't think, had numbers, but
9 there's a page, one, two, three -- the fourth
10 page in, there's op X leader, et cetera, a
11 list of names.
12 A. Yes.
13 Q. Yes, that page.
14 Just to identify who some of
15 these folks were that we haven't talked about
16 before today, Jim Parker, who was that?
17 A. Jim Parker was the Six Sigma
18 leader for the Mallinckrodt plant down in
19 St. Louis.
20 Q. Okay. Is that a quality
21 control function or --
22 A. No, it's system optimization.
23 Q. Okay. And Charity Aranda?
24 A. Charity Aranda was a customer
25 service rep who -- she -- she was still in

Page 221

1 the customer service organization, but she
2 was doing more data query as we were trying
3 to develop the stuff to understand what data
4 we were dealing with for the suspicious order
5 monitoring so we could try to come up with
6 formulas that made sense.
7 Q. Okay. How about Angela Parker?
8 A. Angela Parker was a programmer.
9 Q. Okay. Lois Cahill?
10 A. Lois Cahill was a customer
11 service rep.
12 Q. Cheryl Nelson?
13 A. Cheryl Nelson was a customer
14 service rep, as was Camille Pokorny --
15 Q. Okay.
16 A. -- and Eileen Spalding was from
17 Hobart.
18 Q. Okay. Great.
19 And the next page indicates the
20 event -- the initial event occurred
21 January 20 to 21 of 2009, correct?
22 A. Correct.
23 Q. There's a flow chart on the
24 following page that in the upper left-hand
25 corner begins with "customer prepares and

Page 222

1 submits 222 form to Hazelwood," correct?
2 A. Correct.
3 Q. And that next step is that that
4 form is received by customer service and
5 reviewed, and then there's an "and" and then
6 C/T.
7 Do you know what that means?
8 A. I can't read that.
9 Q. Okay. Yeah, it's -- I can read
10 it, but I'm not sure --
11 A. I need my X-ray glasses.
12 Q. All right. I'm not sure I know
13 what it says.
14 Well, let's proceed beyond
15 that.
16 Do you know the purpose that
17 this flow chart served in the presentation?
18 A. Yes.
19 Q. What was it?
20 A. We tried to get our 222 forms
21 cleared within 24 hours of shipment. This
22 was an example of all the steps we had to go
23 through to clear those 222 forms. So we
24 wanted to evaluate them and determine which
25 were value-added and which were not so we

Page 223

1 could streamline the process.
2 Q. Okay. Do you recall which were
3 ultimately determined to be dispensable?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: No, I would have
7 to compare for which steps.
8 What we actually ended up doing
9 was we had one customer service clerk
10 at the time clearing the forms for us,
11 and what we ended up doing is getting
12 a report from IS. Once the last line
13 was shipped on an order, that order
14 number appeared on a report, and then
15 the customer service reps pulled the
16 222 form and cleared it, rather than
17 clearing each line as they shipped.
18 So feasibly you could have
19 touched one form eight times if it
20 took eight different shipments to get
21 that entire order out of the -- out
22 the door.
23 And DEA did not require that.
24 As long as the form was completed
25 after the last line item was shipped,

Page 224

1 you were in compliance.
2 QUESTIONS BY MR. GOTTO:
3 Q. Okay. And so when you say
4 "touched the form," what do you mean by that?
5 A. Go and pull it out of a file
6 cabinet, and then go into the computer and
7 look up the order number and find that line
8 item, and then compare that line item to the
9 item on the 222 form, and then annotate the
10 form with the quantity shipped and the date
11 shipped.
12 Q. Okay. So if a 222 form
13 contained eight line items -- which they
14 could contain that many, correct?
15 A. Yeah, six or eight. I don't
16 remember exactly.
17 Q. Okay. Well, let's say six.
18 A. But they were multiple.
19 Q. Okay. So let's say it
20 contained six line items.
21 A. Uh-huh.
22 Q. And there would be -- each line
23 item would refer to a particular API that was
24 being ordered, correct?
25 A. A particular SKU.

Page 225

1 Q. A particular SKU. Okay.
2 A. So they could all be for oxy,
3 but different strengths and different bottle
4 sizes.
5 Q. Okay. Or it could be for a
6 variety of different APIs, correct?
7 A. Yes. Correct.
8 Q. And it would reflect what the
9 maximum order amount could be consistent with
10 the 222 for that line, correct?
11 A. The customer order quantity in
12 the computer, when they place the initial
13 order, must match the line item quantity
14 ordered on the 222 form.
15 Q. Okay. And those could be
16 different quantities for each of the six
17 lines, correct?
18 A. Yes.
19 Q. And so am I understanding you
20 correctly that ultimately the conclusion
21 reached was that the customer service rep
22 checking the 222 form against the order
23 actually being shipped could do that at the
24 time that the final -- the sixth of the six
25 lines --

<p style="text-align: right;">Page 226</p> <p>1 A. Right.</p> <p>2 Q. -- was shipped?</p> <p>3 A. Right.</p> <p>4 Q. So would that mean that the</p> <p>5 first or the second or the third may have</p> <p>6 already been shipped?</p> <p>7 A. Correct.</p> <p>8 Q. And so what would happen then</p> <p>9 if there turned out to be a problem with one,</p> <p>10 two or three when the customer service rep</p> <p>11 went and looked at the form 222?</p> <p>12 MR. DAVISON: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: If the quantity</p> <p>15 shipped was less than the quantity</p> <p>16 ordered, then we had to find out from</p> <p>17 Hobart why that was. Was there a</p> <p>18 carton that was damaged and it wasn't</p> <p>19 safe to put it in transit, that kind</p> <p>20 of thing.</p> <p>21 So we annotated the form with</p> <p>22 the quantity that was actually</p> <p>23 shipped, and then the customer would</p> <p>24 receive a credit for the quantity that</p> <p>25 didn't get shipped.</p>	<p style="text-align: right;">Page 228</p> <p>1 the order. And then Eileen Spaulding would</p> <p>2 have had to have gotten involved up there and</p> <p>3 gotten in touch with whoever to resolve the</p> <p>4 issue.</p> <p>5 Q. Okay. If you turn two pages</p> <p>6 after the flow chart we were just looking at,</p> <p>7 the page that has best-case scenario on the</p> <p>8 top?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. It says, "In an ideal</p> <p>11 state, the 222 process would be a standard</p> <p>12 process to identify a sequence and minimize</p> <p>13 touches, errors, exceptions and issues</p> <p>14 located in the forms to better handle the</p> <p>15 volume and better utilize our resources and</p> <p>16 comply with DEA requirements."</p> <p>17 A. Uh-huh.</p> <p>18 Q. So by referencing an ideal</p> <p>19 state, this seems to suggest that there were</p> <p>20 some issues that kept this from being the</p> <p>21 case.</p> <p>22 A. There were.</p> <p>23 Q. What were they?</p> <p>24 A. Aside from human error, you</p> <p>25 know, or I didn't read that right, I thought</p>
<p style="text-align: right;">Page 227</p> <p>1 And DEA didn't care if it was</p> <p>2 less than, as long as it wasn't more.</p> <p>3 QUESTIONS BY MR. GOTTO:</p> <p>4 Q. And what if it was more than</p> <p>5 what was on the 222 form?</p> <p>6 MR. DAVISON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: You can't -- you</p> <p>9 can't ship.</p> <p>10 QUESTIONS BY MR. GOTTO:</p> <p>11 Q. So if the process was that the</p> <p>12 customer service rep would -- would go</p> <p>13 through this verification at the end, when</p> <p>14 the final line was shipped --</p> <p>15 A. Uh-huh.</p> <p>16 Q. -- what was the safeguard to be</p> <p>17 certain that on any of the prior lines there</p> <p>18 hadn't been an overshipment?</p> <p>19 A. There -- when the Hobart team</p> <p>20 ship confirms the order, they had to go line</p> <p>21 by line and indicate the quantity that they</p> <p>22 shipped.</p> <p>23 If the quantity that they</p> <p>24 shipped exceeded the quantity ordered, the</p> <p>25 system would not allow them to ship confirm</p>	<p style="text-align: right;">Page 229</p> <p>1 it was a 5 and it was a 7. But our biggest</p> <p>2 issue was we had an initiative to get all 222</p> <p>3 forms cleared within 24 hours of the last</p> <p>4 shipment.</p> <p>5 A couple of years before I got</p> <p>6 there, they assigned one person the job of</p> <p>7 clearing all the 222 forms. And over the</p> <p>8 course of the years, we realized that that</p> <p>9 wasn't a reasonable expectation. The volume</p> <p>10 was just too great.</p> <p>11 So one of the changes we made</p> <p>12 is if you enter the form, you clear -- or if</p> <p>13 you enter the order, you clear your 222 form.</p> <p>14 So each day every customer service rep got a</p> <p>15 report of which orders had their last line</p> <p>16 shipped, and then they pulled those 222 forms</p> <p>17 and cleared them before they went home that</p> <p>18 day.</p> <p>19 Q. And what does it mean to say</p> <p>20 "clear the form"?</p> <p>21 A. For every line item there's an</p> <p>22 NDC number, the code, the Mallinckrodt code,</p> <p>23 for the product, the English description and</p> <p>24 the quantity ordered.</p> <p>25 When you clear the form,</p>

Page 230

1 there's -- you put the date that that product
 2 was placed in shipment and the quantity that
 3 you shipped. Once all of those lines are
 4 filled, that 222 form is cleared.
 5 Q. Okay. And that -- the process
 6 was that the customer service rep would
 7 conclude that -- that process of clearing, as
 8 you just described it, on the business day
 9 following the last shipment?
 10 A. It depended on the timing.
 11 Hobart was an hour ahead of us, so I think
 12 our reports ran about three o'clock. But if
 13 something got shipped late -- because there
 14 was, you know, an occasional time when an
 15 order didn't get ship confirmed in time to
 16 show up on our report today, so it would show
 17 up on the report tomorrow.
 18 Q. Okay. So in any event, it
 19 would be cleared no later than the business
 20 day after ship --
 21 A. The next business day, correct.
 22 Q. Okay. Two pages later there's
 23 a page called ah-ha moments?
 24 A. Uh-huh.
 25 Q. And the first ah-ha moment is,

Page 231

1 "222s don't have to be cleared after each
 2 line item is shipped."
 3 And that's what you were just
 4 discussing, correct?
 5 A. Yes.
 6 Q. And so do you recall how
 7 that ah-ha came about, who pointed this out?
 8 MR. DAVISON: Objection to
 9 form.
 10 THE WITNESS: We just asked the
 11 questions, "Why do we -- where does it
 12 say in the regulations that we have to
 13 clear each line as it ships?"
 14 And then Karen Harper
 15 investigated and came back and said,
 16 "It doesn't say that. We don't have
 17 to do that." So that was our first
 18 ah-ha moment.
 19 QUESTIONS BY MR. GOTTO:
 20 Q. Okay. Next ah-ha moment,
 21 "error rates are such that double-checks can
 22 be eliminated. If we do make an error, deal
 23 with it then."
 24 A. Yes.
 25 Q. Now, what does that mean?

Page 232

1 A. When multiple people were
 2 clearing the same form, they could write
 3 something on the wrong line. You know, like
 4 they might be clearing line 3 and
 5 accidentally writing the quantity on line 4.
 6 So they were, you know, just human error kind
 7 of things.
 8 Q. So when it says, "Error rates
 9 are such that double-checks can be
 10 eliminated," that would seem to suggest that
 11 the error rates were so low that it was not
 12 necessary to double-check them?
 13 MR. DAVISON: Objection to
 14 form.
 15 THE WITNESS: I don't know that
 16 that was the case.
 17 QUESTIONS BY MR. GOTTO:
 18 Q. Does that mean that if the 222s
 19 are not cleared line by line but are only
 20 cleared after the last shipment, then the
 21 error rates would be so low --
 22 A. Yes.
 23 Q. -- that it's not necessary to
 24 double-check them?
 25 A. I believe so.

Page 233

1 MR. DAVISON: Objection to
 2 form.
 3 QUESTIONS BY MR. GOTTO:
 4 Q. The final items says, "222s
 5 from clinics with hold for shipping
 6 instructions relative to multiple shipments
 7 on multiple dates performed were not in
 8 compliance with DEA regulations."
 9 What does that mean?
 10 A. Methadone clinics wanted to
 11 submit one 222 form for 500 cases of
 12 methadone, but they only wanted to submit one
 13 form. So on line 1, they'd say they'd want a
 14 hundred, and line 2 would -- you know, it's
 15 all the same product, but I want a hundred on
 16 this date, a hundred on this date, a hundred
 17 on this date. And that was not in compliance
 18 with DEA requirements. You had to submit one
 19 form per shipment.
 20 Q. Okay. And prior to this -- to
 21 this event, had Mallinckrodt accepted the
 22 multiple shipments on a single form?
 23 MR. DAVISON: Objection to
 24 form.
 25 THE WITNESS: I believe -- I

<p style="text-align: right;">Page 234</p> <p>1 believe we may have been, but I'm not 2 positive. 3 QUESTIONS BY MR. GOTTO: 4 Q. Okay. All right. And if you 5 turn to the last page, or the next to last 6 page, before questions, there's a page that 7 says, "Barriers to success, significant 8 workload increase due to oxycodone 9 situation." 10 What was the oxycodone 11 situation that created the significant 12 workload increase? 13 MR. DAVISON: Objection to 14 form. 15 THE WITNESS: There was a 16 national shortage of oxycodone, so 17 there was not enough to supply the 18 marketplace either through us or any 19 other oxycodone manufacturer. The DEA 20 had cut quotas back sharply, so we had 21 to place customers on allocation. So 22 we didn't want to not give you any, 23 but we tried to be prudent in giving 24 you some so that there would be 25 product available for the other</p>	<p style="text-align: right;">Page 236</p> <p>1 probably blasphemy, but why do we continue to 2 service our methadone clinics as 3 individuals?" 4 Do you see that? 5 A. Uh-huh. 6 Q. "Why can't we have them 7 serviced through the DC efforts of McKesson, 8 Cardinal and/or ABC?" 9 A. Correct. 10 Q. Who was ABC? 11 A. AmerisourceBergen, I believe. 12 Q. Okay. And what do you mean 13 when you say "have them serviced through the 14 DC efforts" of one of those entities? 15 A. Methadone clinics are many 16 throughout the country, and each clinic 17 places their own order for methadone, so the 18 volume of orders coming into the customer 19 service group is staggering sometimes. And 20 this was just a proposal of why can't we ship 21 methadone to the distributors and let the 22 distributors ship methadone to the clinics. 23 Q. Okay. And why did you think 24 that was probably blasphemy? 25 A. Because then the -- we never</p>
<p style="text-align: right;">Page 235</p> <p>1 customers, too. 2 QUESTIONS BY MR. GOTTO: 3 Q. Okay. And so that allocation 4 function created additional work? 5 A. Yes. 6 Q. Any other aspects of the 7 oxycodone situation that created -- 8 A. No, that was the only oxycodone 9 situation, was the shortage. 10 MR. GOTTO: Okay. Why don't we 11 take a break. 12 VIDEOGRAPHER: We are going off 13 the record at 2:41 p.m. 14 (Off the record at 2:41 p.m.) 15 VIDEOGRAPHER: We are back on 16 the record at 2:56 p.m. 17 (Mallinckrodt-Stewart Exhibit 18 26 marked for identification.) 19 QUESTIONS BY MR. GOTTO: 20 Q. Ms. Stewart, Exhibit 26 is a 21 single-page e-mail bearing Bates 22 MNK-T1_0006305000. It is an e-mail from you 23 to Michael Phenev and James Champion from 24 June of 2009. 25 And in it you say, "This is</p>	<p style="text-align: right;">Page 237</p> <p>1 gave up our methadone. That was a big 2 business for Mallinckrodt, the addiction 3 treatment, and I don't think that they'd ever 4 want to give it up, you know, so -- but from 5 a workflow standpoint, something in my mind 6 that was worth exploring. 7 Q. Okay. Did you get a response 8 on this idea? 9 A. I did. 10 Q. And what was it? 11 A. Nope. 12 (Mallinckrodt-Stewart Exhibit 13 27 marked for identification.) 14 QUESTIONS BY MR. GOTTO: 15 Q. Okay. Exhibit 27 is a 16 single-page series of e-mails bearing Bates 17 MNK-T1_0000473726. 18 The earlier e-mail from 19 Ms. Harper, under the word "redacted" it 20 says, "Do you agree that as part of our 21 ongoing commitment to keep sales and 22 marketing involved, we would send an advance 23 copy to them?" 24 And do you understand what 25 advance copy is -- Ms. Harper is referring</p>

Page 238

1 to?

2 A. No.

3 MR. DAVISON: Objection to

4 form.

5 THE WITNESS: No, I do not.

6 QUESTIONS BY MR. GOTTO:

7 Q. Okay. In your responsive

8 e-mail you say, "Since API could be affected

9 by this as well, we should probably include

10 their sales reps in addition to John's and

11 Ken McBean's. I'll get you a list."

12 Do you see that?

13 A. Uh-huh.

14 Q. And so API would be affected by

15 what? Or could be affected by what?

16 A. I don't recall.

17 Q. Okay. And when you say "their

18 sales reps," you mean API sales reps?

19 A. Correct.

20 Q. Okay. And so who was Ken

21 McBean?

22 A. I don't remember.

23 Q. Okay. Is the John John Adams?

24 A. Probably.

25 Q. Okay.

Page 239

1 A. Uh-huh.

2 Q. And so were his sales reps not

3 API sales reps?

4 A. His sales reps were dosage

5 sales reps.

6 Q. Okay. Okay. Okay. You can

7 set that aside.

8 (Mallinckrodt-Stewart Exhibit

9 28 marked for identification.)

10 QUESTIONS BY MR. GOTTO:

11 Q. Exhibit 28 is a single-page

12 e-mail bearing Bates MNK-T1_0000268346. It's

13 from Robyn McHale.

14 Who was Robyn McHale?

15 A. She was a programmer.

16 Q. Okay. And addressed to a

17 number of individuals, including yourself,

18 one of whom is George Saffold.

19 Who was that?

20 A. He was my boss at the time.

21 There was a reorganization in the logistics

22 group, and George came in as director over

23 customer service specifically.

24 Q. Okay. So was Mr. Pheney still

25 in the chain?

Page 240

1 A. He was still in logistics but

2 not specific -- there was -- George was

3 between us and Michael.

4 Q. Okay.

5 A. Okay.

6 Q. And approximately when did that

7 happen, that Mr. Saffold became your direct

8 report?

9 A. I don't remember.

10 Q. Okay. And who was Pat

11 D'Angelo?

12 A. She was a bulk customer service

13 rep.

14 Q. So she was a bulk customer

15 service rep?

16 A. Uh-huh.

17 Q. At this time, September 28,

18 '09, were you the customer service manager

19 for dosage or for bulk?

20 A. I'm not positive.

21 Q. Okay.

22 A. I'd be guessing.

23 Q. Okay. When you switched from

24 customer service manager for dosage to bulk,

25 do you recall what the circumstances were

Page 241

1 that caused that change to happen?

2 MR. DAVISON: Objection to

3 form.

4 THE WITNESS: I think it was

5 just a reorganization within the --

6 because George came into the

7 organization, and so he kind of

8 shuffled things around to get every --

9 all of the managers familiar with all

10 of the aspects of the business.

11 QUESTIONS BY MR. GOTTO:

12 Q. Okay. All right. Ms. McHale's

13 e-mail says, "Project suspicious order

14 monitoring will be implemented today, but

15 processing will not begin until October 7,

16 2009," right?

17 A. Correct.

18 Q. And is that consistent with

19 your recollection that the -- that the -- the

20 suspicious order monitoring program that the

21 team had been working on was implemented in

22 late September and -- with processing

23 beginning in early October of '09?

24 MR. DAVISON: Objection to

25 form.

Page 242

1 THE WITNESS: I'm -- I suppose
2 it was.
3 QUESTIONS BY MR. GOTTO:
4 Q. Okay. And I think we've seen
5 some materials here earlier today that
6 indicate that the team was working on the SOM
7 by mid-2008, correct?
8 A. Uh-huh.
9 Q. So fair to say that it took
10 over a year?
11 A. Took a long time.
12 MR. DAVISON: Objection to
13 form.
14 THE WITNESS: Yeah. Yes.
15 QUESTIONS BY MR. GOTTO:
16 Q. Do you recall why it took so
17 long?
18 A. I think because of all the
19 iterations and the logic we were trying to
20 implement, kind of trying to play devil's
21 advocate and come up with all of the possible
22 scenarios that an order might be considered
23 suspicious.
24 Q. Okay. And so during the period
25 that the team was working on the SOM but

Page 243

1 before it was implemented, do I understand
2 you correctly with respect to dosage, the --
3 the customer service reps could identify or
4 could call into question an order based on
5 their own personal reaction to it?
6 A. Yes.
7 Q. And during that period, do you
8 have any understanding as to how, if any, a
9 bulk order could be called into question by a
10 customer service rep?
11 A. I'm sure it was the same, a
12 customer service rep's knowledge of the
13 business they were taking care of, but I
14 don't have any personal information or
15 knowledge, excuse me, of a report -- or an
16 order that was placed on hold based on a
17 customer service rep's --
18 Q. Okay. So in terms of the bulk
19 business, do you recall if you had customer
20 service manager responsibility during any
21 period prior to the time that the SOM was
22 implemented in the fall of 2009?
23 MR. DAVISON: Objection to
24 form.
25 THE WITNESS: I do not.

Page 244

1 QUESTIONS BY MR. GOTTO:
2 Q. Okay. And with respect to your
3 responsibilities as customer service manager
4 as to dosage, do you recall if you were in
5 that role during any period when the
6 suspicious order monitoring program that had
7 been established by the team had been
8 implemented?
9 A. I do not.
10 Q. Okay. You can set that aside.
11 (Mallinckrodt-Stewart Exhibit
12 29 marked for identification.)
13 QUESTIONS BY MR. GOTTO:
14 Q. Exhibit 29 is a one-page series
15 of e-mails bearing Bates MNK-T1_0000303636.
16 And these are e-mails dated October 7, 2009,
17 which I believe the prior exhibit indicated
18 would be the day that the -- the suspicious
19 order monitoring program would become active,
20 correct?
21 A. Uh-huh.
22 Q. The top of the page is a -- an
23 e-mail from Robyn McHale to Jim Rausch and
24 you, although it says, "Jim, there are a
25 little over 100 orders on hold between you

Page 245

1 and bulk. You should receive your first hold
2 report at 12:30. If you have any issues or
3 question, please don't hesitate to contact
4 me."
5 So this is October 7, 2009.
6 And when Ms. McHale says, "Jim, there are a
7 little over 100 orders on hold between you
8 and bulk," does that indicate to you that at
9 that time Mr. Rausch had responsibility for
10 dosage?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: Yes.
14 QUESTIONS BY MR. GOTTO:
15 Q. Okay. And would that mean that
16 at that time you had responsibility for bulk?
17 A. Uh-huh.
18 Q. Does that refresh your
19 recollection at all as to when you took
20 responsibility for bulk?
21 A. Not specifically, but in the
22 general time frame.
23 Q. So does it appear that at least
24 by October 7 of '09 --
25 A. Yes.

Page 246

1 Q. -- you no longer had dosage
 2 responsibility but had bulk responsibility?
 3 A. Had bulk, yes.
 4 Q. Okay. And this e-mail
 5 indicates a little over 100 orders between
 6 dosage and bulk.
 7 Do you recall when the SOM
 8 first became active how many orders were on
 9 hold for bulk?
 10 A. No, I don't.
 11 Q. And would this have been orders
 12 on hold for a period of time, or would this
 13 have been orders just current to that date
 14 that had been placed on hold; do you know?
 15 MR. DAVISON: Objection to
 16 form.
 17 THE WITNESS: I don't know.
 18 QUESTIONS BY MR. GOTTO:
 19 Q. A hundred orders would be a
 20 fairly significant number of orders to work
 21 through, wouldn't it?
 22 MR. DAVISON: Objection to
 23 form.
 24 THE WITNESS: On the dosage
 25 side, that would be possibly average

Page 247

1 for the number of orders in a day or
 2 two. On the bulk side, that would be
 3 outrageous.
 4 QUESTIONS BY MR. GOTTO:
 5 Q. Okay. So on the dosage side,
 6 though, would that be the total number of
 7 orders or the number of orders that were on
 8 hold?
 9 A. I would -- according to this, I
 10 would interpret that as saying orders on
 11 hold.
 12 Q. Okay. And in your experience,
 13 you would think that that would be a
 14 reasonable number to expect to be a daily
 15 average?
 16 MR. DAVISON: Object to form.
 17 THE WITNESS: Of hold orders?
 18 QUESTIONS BY MR. GOTTO:
 19 Q. Yes.
 20 A. I would -- since the process
 21 was so new, I don't know that I had an
 22 expectation of what the daily average would
 23 be at this point.
 24 Q. Okay. Did you ever come to
 25 have any understanding as to what the daily

Page 248

1 average was for dosage orders that were
 2 identified as peculiar through the SOM?
 3 A. No, because I was not in dosage
 4 anymore, so I don't know how many orders Jim
 5 was dealing with.
 6 Q. Okay. And on the bulk side, do
 7 you have any sense on average of how many
 8 orders were identified as peculiar on a daily
 9 basis?
 10 A. My recollection is that there
 11 were only one or two. Very small numbers.
 12 Q. Okay. You can put that aside.
 13 (Mallinckrodt-Stewart Exhibit
 14 30 marked for identification.)
 15 QUESTIONS BY MR. GOTTO:
 16 Q. Exhibit 30 is a single-page
 17 series of e-mails bearing Bates
 18 MNK-T1_0000278394, e-mails from November 6th
 19 of 2009.
 20 The e-mail on the top of the
 21 page is from you to Karen Harper, Jim Rausch
 22 and George Saffold, and you begin it by
 23 saying, "I've reviewed the first two QSP
 24 documents and have highlighted and/or placed
 25 question marks by some items I think we need

Page 249

1 to discuss further."
 2 What are you referring to when
 3 you say "QSP documents"?
 4 A. It's a quality document. I
 5 can't remember what the SP stands for. But
 6 that's how the procedure documents are
 7 documented, with QSP numbers, the formal
 8 procedure documents.
 9 Q. Okay. So would these have --
 10 would you be referring there to documents
 11 that describe the SOM procedure?
 12 A. At least a draft.
 13 Q. Okay. Okay. You can set that
 14 aside.
 15 (Mallinckrodt-Stewart Exhibit
 16 31 marked for identification.)
 17 QUESTIONS BY MR. GOTTO:
 18 Q. Exhibit 31 is a single-page
 19 series of e-mails bearing Bates
 20 MNK-T1_0000300118. And the e-mail toward the
 21 bottom, in the bottom half of the first -- of
 22 the page, from Eileen Spaulding to Karen
 23 Harper on March 1 of 2010, do you see that?
 24 A. Correct. Yes.
 25 Q. And Ms. Spaulding says, "Karen,

Page 250

1 is our suspicious order monitoring program up
2 and running, question mark?"
3 Do you see that?
4 A. Uh-huh.
5 Q. Now, this is dated March 1,
6 2010, so this is over four months from when
7 the procedure was implemented, correct?
8 A. Correct.
9 Q. Is there a reason that
10 Ms. Spalding would not have been aware by
11 this point as far as whether the program was
12 up and running?
13 MR. DAVISON: Objection to
14 form.
15 THE WITNESS: I don't know.
16 Eileen was not involved in the release
17 of orders, so she probably did not
18 receive a copy of the report and
19 wasn't aware of its content.
20 QUESTIONS BY MR. GOTTO:
21 Q. Okay. Okay. You can set that
22 aside.
23 (Mallinckrodt-Stewart Exhibit
24 32 marked for identification.)
25

Page 251

1 QUESTIONS BY MR. GOTTO:
2 Q. Exhibit 32 is a single page of
3 e-mails bearing Bates MNK-T1_0000301439.
4 In the bottom part of the page
5 there is an e-mail from you to Steve Horner
6 copying some other folks. "Steve, I inquired
7 about turning the exceeds 30-day Cum Avg flag
8 logic off from the report, but before I
9 submit an ASR, I need to verify that the
10 logic for calculating the target average
11 quantity is sum of orders for past 18 months
12 divided by the total number of orders in that
13 period."
14 Correct?
15 A. Correct.
16 Q. What is -- what are you
17 referring to when you talk about turning the
18 exceeds 30-day Cum Avg flag logic off?
19 A. It was a cumulative average
20 flag, and I believe that we were questioning
21 the validity of the data we were receiving in
22 relation to the intent that we wanted.
23 That's my speculation.
24 Q. What was the intent, and in
25 what way were you concerned that the data was

Page 252

1 not reliable?
2 MR. DAVISON: Objection to
3 form.
4 THE WITNESS: I don't recall.
5 QUESTIONS BY MR. GOTTO:
6 Q. You don't recall either -- what
7 the intent was of requesting that cumulative
8 average?
9 A. Well, the original intent would
10 have been to try to highlight customer orders
11 that exceeded a specific quantity, but I
12 think once the data started to run and we --
13 and this is purely speculation -- and we
14 started to see the data on the report, we
15 questioned if that was a good metric.
16 Q. Okay. And what was the aspect
17 of the output of the report that caused you
18 to question whether it was a good metric?
19 MR. DAVISON: Objection to
20 form.
21 THE WITNESS: I think -- I'm
22 not positive.
23 QUESTIONS BY MR. GOTTO:
24 Q. Okay. Mr. Rausch responds to
25 your e-mail by saying, "Cathy, should it be 2

Page 253

1 X?"
2 And you respond that, "I think
3 the expectation is that 2 X is an appropriate
4 threshold limit, and I do believe the program
5 is doing that calculation properly."
6 Correct?
7 A. Correct.
8 Q. And this is, again, several
9 months after the SOM was implemented,
10 correct?
11 A. Right.
12 Q. Does this refresh your
13 recollection as to whether the factor that
14 was used as part of the SOM when it was
15 initially implemented was two times some
16 historical average?
17 A. Based on the content in this
18 e-mail, I would assume so.
19 Q. Okay. Okay. You can set that
20 aside.
21 (Mallinckrodt-Stewart Exhibit
22 33 marked for identification.)
23 QUESTIONS BY MR. GOTTO:
24 Q. Exhibit 33 is a multi-page
25 string of e-mails beginning with Bates

Page 254

1 MNK-T1_0000279975.
2 The only question I have for
3 you is -- concerns your e-mail that's on the
4 first page of that exhibit in the middle of
5 the page that says, "How's progress on the
6 revised suspicious order monitoring program
7 going?"
8 Do you see that?
9 A. Uh-huh.
10 Q. Now, this e-mail is dated
11 August 9, 2010.
12 A. Yes.
13 Q. Do you recall there being
14 revisions to the specific -- to the
15 suspicious order monitoring program under
16 consideration in August of 2010?
17 A. I can't say for sure.
18 Q. Do you recall any revisions to
19 the SOM being made after it was implemented
20 in October of 2010 -- 2009?
21 A. I don't know that.
22 Q. Okay. Do you recall any
23 revisions to the SOM as initially implemented
24 being suggested by anyone, to your knowledge?
25 MR. DAVISON: Objection to

Page 255

1 form.
2 THE WITNESS: No.
3 QUESTIONS BY MR. GOTTO:
4 Q. Okay. Any idea what would have
5 prompted you to ask Karen Harper how progress
6 on the revised suspicious order monitoring
7 program was going in August of 2010?
8 A. Based on the title on these
9 e-mails, these are talking about
10 international orders, so my guess is that we
11 were trying to expand the scope of the
12 suspicious order monitoring program.
13 Q. Okay. But you don't --
14 independent of that title, you don't have a
15 recollection of that?
16 A. I don't have any recollection.
17 Q. Okay. You can set that aside.
18 (Mallinckrodt-Stewart Exhibit
19 34 marked for identification.)
20 QUESTIONS BY MR. GOTTO:
21 Q. Exhibit 34 is a five-page
22 document beginning on Bates
23 MNK-T1_0000477889. It's encaptioned
24 "Suspicious Order Monitoring Program, Dosage
25 Products Shipments From Hobart, Activities

Page 256

1 10/2008 through 6/2010," with the 6/2010 date
2 struck through.
3 Do you see that?
4 A. Uh-huh.
5 Q. Updated 8/2010.
6 First question, do you
7 recognize any of the handwriting on this
8 document?
9 A. I believe the handwriting is
10 that of Karen Harper.
11 Q. Okay. On the first page in
12 the -- about the middle of the page, there's
13 handwriting that says, "DEA Albany verbally
14 requests quarterly updates of all orders we
15 have reviewed as peculiar."
16 Do you see that?
17 A. Yes, I do.
18 Q. And do you recall being aware
19 at any point of that request from DEA Albany?
20 A. No.
21 Q. Do you recall being aware at
22 any point that any updates were being
23 provided to DEA of orders that had been
24 reviewed as peculiar?
25 MR. DAVISON: Objection. Form.

Page 257

1 THE WITNESS: No.
2 QUESTIONS BY MR. GOTTO:
3 Q. Okay. If you turn to the third
4 page of that exhibit, the top of page 3 of 4,
5 there's an entry under the date 7/13/2009.
6 Do you see that?
7 A. Yes.
8 Q. Okay. And it says, "Work
9 continues with IS on algorithms. E-mail
10 follows from Cathy Stewart. I'm getting
11 confused," series of dots, "can you set up
12 some time to talk about this tomorrow if this
13 doesn't make sense?"
14 It goes on to say, "Numbers
15 have to be the sum of actual order for the
16 respective months. Numbers have to be in
17 monthly buckets. As I see it," series of
18 dots, and then there's "month" and a series
19 of numeric entries.
20 A. Uh-huh.
21 Q. Below that there's text that
22 states, "This was. We can see that this
23 customer has gradually increased their
24 ordering quantity from 100 a month to 175 per
25 month over the course of the past two years.

Page 258

1 There may be a legitimate business reason for
2 this, but we need to investigate and make
3 sure they're not just gradually increasing
4 their order quantities to not get caught by
5 the 2 X formula threshold."
6 Do you see that?
7 A. Uh-huh.
8 Q. Do you recall sending this
9 e-mail?
10 A. No.
11 Q. Do you recall ever expressing
12 any concerns regarding whether a customer
13 could avoid the -- strike that.
14 Do you recall ever expressing
15 any concerns requesting whether a customer
16 could, through gradual increases, avoid
17 getting caught by the 2 X formula threshold?
18 MR. DAVISON: Objection to
19 form.
20 THE WITNESS: Yes.
21 QUESTIONS BY MR. GOTTO:
22 Q. And in what context can you
23 recall expressing that concern?
24 A. When we were trying to think of
25 ways that customers could circumvent the

Page 259

1 system and if there were any algorithms we
2 could put in place that would catch those.
3 Q. Okay. And when you say "we" in
4 that setting, you mean the SOM team?
5 A. Yes.
6 Q. Okay. And were there any
7 algorithms that were employed to try to
8 address that concern?
9 A. I don't recall.
10 Q. Okay. If you turn to the next
11 page, page 4 of 5, there's an entry under
12 4/30/10, about two-thirds of the way down the
13 page.
14 A. Uh-huh.
15 Q. It says, "Peculiar order
16 calculation changed from 2 X factor to 3 X
17 factor."
18 Do you see that?
19 A. Uh-huh.
20 Q. Do you recall that occurring in
21 April of 2010, the factor changing from 2 X
22 to 3 X?
23 A. No, I don't.
24 Q. Do you recall there being any
25 discussions at any point to which you were a

Page 260

1 party concerning whether the factor should be
2 changed to 3 X?
3 A. No, I don't recall.
4 Q. In the course of the
5 formulation of the SOM as it was implemented
6 in October of 2009, do you recall anyone on
7 the team at any point suggesting that the
8 appropriate factor should be 3 X rather than
9 2 X?
10 A. I recall discussion about that,
11 2 X versus 3 X, but I don't recall who
12 brought it up specifically or what the
13 outcome was.
14 Q. Okay. And I think as we've
15 already seen, when the SOM was initially
16 implemented in October of 2009, the factor
17 was 2 X, correct?
18 A. 2 X, uh-huh.
19 Q. Who would have had authority to
20 change that from 2 X to 3 X?
21 A. I don't recall.
22 Q. Now, the concern regarding a
23 gradual increase --
24 A. Uh-huh.
25 Q. -- being a means by -- to

Page 261

1 circumvent the operation of the -- of the
2 SOM, that concern would, if anything, be
3 heightened if the factor were 3 X compared to
4 2 X, wouldn't it?
5 MR. DAVISON: Objection to
6 form.
7 THE WITNESS: I believe so.
8 QUESTIONS BY MR. GOTTO:
9 Q. So after April of 2010, there
10 was still a period of time when you
11 functioned as customer service manager for
12 API, correct?
13 A. Correct.
14 Q. And so during that period of
15 time after April of 2010, you would have
16 received on a daily basis the peculiar order
17 report, correct?
18 A. Correct.
19 Q. Were you aware after April
20 of 2010 that the -- that the factor used to
21 generate that report had been changed from
22 2 X to 3 X?
23 MR. DAVISON: Objection to
24 form.
25 THE WITNESS: I would assume

Page 262

1 so.
2 QUESTIONS BY MR. GOTTO:
3 Q. Okay. But you don't recall
4 that?
5 A. I don't recall being
6 specifically told that.
7 Q. Okay. Do you know how you
8 would have become aware of it?
9 MR. DAVISON: Objection to
10 form.
11 THE WITNESS: I'd be
12 speculating.
13 QUESTIONS BY MR. GOTTO:
14 Q. Okay. Do you know if the
15 change from 2 X to 3 X on the factor had any
16 implication for how you or the CSRs that you
17 supervised reviewed the peculiar order
18 reports that you received after April
19 of 2010?
20 MR. DAVISON: Objection.
21 THE WITNESS: I don't believe
22 so.
23 QUESTIONS BY MR. GOTTO:
24 Q. Do you know if the CSRs that
25 you supervised were aware that the factor had

Page 263

1 been changed from 2 X to 3 X?
2 MR. DAVISON: Objection to
3 form.
4 THE WITNESS: I don't believe
5 so.
6 QUESTIONS BY MR. GOTTO:
7 Q. And I'm sorry, do you mean you
8 don't believe they were aware of it?
9 A. I don't believe they were aware
10 of it.
11 Q. Okay. You can set that aside.
12 (Mallinckrodt-Stewart Exhibit
13 35 marked for identification.)
14 QUESTIONS BY MR. GOTTO:
15 Q. Exhibit 35 is a 13-page
16 document beginning with Bates
17 MNK-T1_0000477900, and it's encaptioned
18 "Suspicious Order Monitoring Program, Dosage
19 Product Shipments from Hobart, Activities
20 8/08 through 8/2010."
21 And this appears to be a
22 somewhat more detailed version of the
23 document we just looked at. I have a couple
24 of questions for you on it.
25 On the first page, the entry at

Page 264

1 1/27/2009 at the bottom of the page, it says,
2 "Cathy Stewart begins working with our
3 information service group to develop an
4 electronic system modeled after HDMA
5 guideline, attached, pages 7 and 8."
6 Do you know what the HDMA
7 guideline is?
8 A. I don't remember.
9 Q. Okay. On the next page, page 2
10 of 13, there's an entry 2/13/2009,
11 "Mallinckrodt SOM team conducts a conference
12 call with drug and chemical advisory group,
13 Frank Sapienza and colleagues, to review
14 Mallinckrodt draft revised SOM."
15 Do you recall participating in
16 a conference call with Mr. Sapienza and his
17 colleagues?
18 MR. DAVISON: Objection to
19 form.
20 THE WITNESS: No, I don't.
21 QUESTIONS BY MR. GOTTO:
22 Q. Do you know who he is?
23 A. I believe he's a former DEA
24 agent, but I'm not positive.
25 Q. Okay. If you turn to page 6 of

Page 265

1 13, there's an e-mail 8/10/10 date. Under
2 that it says, "E-mail copy to Pat Duft from
3 Karen Harper."
4 A. Uh-huh.
5 Q. Who was Pat Duft, if you know?
6 A. Pat Duft is one of the
7 attorneys at Mallinckrodt.
8 Q. Okay. And it says, "The
9 suspicious order monitoring team has resumed
10 meetings and is reviewing existing Cognos
11 data to determine how chargeback information
12 could be collected to enhance the program
13 based on DEA conversation detailed below."
14 Do you see that?
15 A. Uh-huh.
16 Q. Do you recall any discussions
17 as part of the SOM team at any point with
18 respect to whether chargeback data could be
19 used to identify peculiar or suspicious
20 orders?
21 A. No, I don't.
22 Q. Do you know if there came a
23 time when chargeback info -- well, strike
24 that.
25 Do you know what chargeback

Page 266

1 information is?
 2 A. No.
 3 Q. Okay. Do you recall ever using
 4 for any purpose any report that was referred
 5 to as a chargeback report?
 6 A. Not an official chargeback
 7 report that would like be generated on a
 8 daily basis or anything. I did get data from
 9 a report that somebody ran for me one time
 10 just to reduce the order quantities to kilos
 11 of API.
 12 Q. Okay. And what was that? A
 13 chargeback report?
 14 A. It was chargeback data. It
 15 wasn't a report.
 16 Q. Okay. Do you know what the
 17 nature is -- was of the chargeback data that
 18 Mallinckrodt compiled with respect to its
 19 distributors?
 20 MR. DAVISON: Objection to
 21 form.
 22 THE WITNESS: No.
 23 QUESTIONS BY MR. GOTTO:
 24 Q. Do you know if there ever came
 25 to be a time that Mallinckrodt used

Page 267

1 chargeback data as part of its suspicious
 2 order monitoring program?
 3 MR. DAVISON: Objection. Form.
 4 THE WITNESS: I don't know.
 5 QUESTIONS BY MR. GOTTO:
 6 Q. If you turn to page 10 of 13,
 7 there is an excerpt from an e-mail from Kate
 8 Muhlenkamp.
 9 Who was Kate Muhlenkamp?
 10 A. She was in the marketing group.
 11 Q. Okay. And down below the
 12 Internet link that's cited, there's a
 13 paragraph that says, "Additionally, it came
 14 to our attention that Sunrise Wholesaler's
 15 DEA license was suspended pending further
 16 investigation."
 17 Is that a circumstance you can
 18 recall being familiar with?
 19 A. Sunrise, the name is familiar,
 20 but I don't know that the circumstances are.
 21 Q. Okay. The following paragraph
 22 says, "The two wholesaler/distributor license
 23 suspensions led us to do a more in-depth
 24 analysis of Covidien's oxycodone sales in the
 25 state of Florida. We specifically focused on

Page 268

1 doctors' offices and pain clinics. It
 2 appears that Harvard and Sunrise were the
 3 dominant players in this market, with over
 4 50 percent of total sales coming from this
 5 market."
 6 Do you recall being aware of
 7 the in-depth analysis of oxycodone sales in
 8 the state of Florida that Ms. Muhlenkamp
 9 refers to in that paragraph?
 10 MR. DAVISON: Objection to
 11 form.
 12 THE WITNESS: No.
 13 QUESTIONS BY MR. GOTTO:
 14 Q. I take it you didn't
 15 participate in that analysis?
 16 A. No.
 17 Q. Okay.
 18 A. I don't believe I did.
 19 Q. Okay. You can set that aside.
 20 (Mallinckrodt-Stewart Exhibit
 21 36 marked for identification.)
 22 QUESTIONS BY MR. GOTTO:
 23 Q. Exhibit 36 is a three-page
 24 string of e-mails beginning with Bates
 25 MNK-T1_0000290583. The subject -- these

Page 269

1 e-mails are from May of 2008, and the subject
 2 matter is Frank's Lab in Ocala, Florida.
 3 Do you recall any issues
 4 regarding Frank's Lab in Ocala, Florida?
 5 A. Not specifically.
 6 Q. Okay. So if we look at the
 7 first e-mail, which -- the earliest in time
 8 on the third page, from Brenda Rehkop to Kate
 9 Muhlenkamp and a copy to you.
 10 Do you see it?
 11 A. Uh-huh.
 12 Q. And it says, "Kate, Joe," at a
 13 certain phone number, "wants to open a new
 14 account for Frank's Labs to purchase opium
 15 powder. They usually order from Medisca,
 16 PCCA or Spectrum, but all of these facilities
 17 are refusing to order opium for him and
 18 stating it is too risky. Joe heard about the
 19 new account in Las Vegas who now purchases
 20 opium directly from Mallinckrodt and wants to
 21 start doing the same thing."
 22 Do you see that?
 23 A. Uh-huh.
 24 Q. Do you recall any of those
 25 circumstances at all?

Page 270

1 A. No.
2 Q. Okay. You forwarded that
3 e-mail to Ms. Harper and Mr. Ratliff for
4 their information, right?
5 A. Correct.
6 Q. And then Mr. Ratliff responded,
7 "Cathy, first, how do we know he's too risky?
8 What is the source? Second, if this is the
9 case, we would be highly criticized by DEA if
10 others in the industry consider him too
11 risky, and we were to provide him a
12 Schedule II."
13 Correct?
14 A. Correct.
15 Q. And Mr. Ratliff there,
16 Schedule II, he's referring to opium being a
17 Schedule II --
18 A. Yes.
19 MR. DAVISON: Objection to
20 form.
21 QUESTIONS BY MR. GOTTO:
22 Q. -- controlled substance?
23 A. Correct.
24 Q. And then you -- you forwarded
25 an e-mail to Ms. Muhlenkamp asking, how can

Page 271

1 we quantify what the other providers have in
2 support of their claim that he's too risky?
3 And Ms. Muhlenkamp ultimately
4 responds, her initial thought is that "the
5 customer might not be worth it to ship to,
6 not just quality-wise but quantity-wise, but
7 I will firm that up tomorrow."
8 Do you recall ever -- what the
9 outcome of this -- this process was?
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: No, I don't.
13 QUESTIONS BY MR. GOTTO:
14 Q. Now, looking back at
15 Ms. Rehkop's first e-mail, who is Medisca?
16 A. Medisca was one of our
17 customers.
18 Q. And PCCA?
19 A. A customer, and so was
20 Spectrum.
21 Q. Okay. So they were all
22 distributor customers of --
23 A. I don't know that they were
24 distributors. They could have been research
25 licenses.

Page 272

1 Q. Okay. And was opium powder a
2 bulk product or a dosage product?
3 A. Opium powder is a dosage
4 product.
5 Q. Okay. And Ms. Rehkop in her
6 e-mail, the last sentence, says, "Joe heard
7 about the new account in Las Vegas who now
8 purchases opium directly from Mallinckrodt."
9 Do you know what she's
10 referring to there?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: I don't. I don't
14 recall.
15 QUESTIONS BY MR. GOTTO:
16 Q. So in terms of parties --
17 customers who would have purchased opium
18 directly from Mallinckrodt, would those have
19 been either distributors or chain pharmacies?
20 A. They -- I'm speculating, but I
21 believe they would have been compounding
22 pharmacies.
23 When patients can't take the
24 dose that's in pill form, for whatever
25 reasons, there are some specialized

Page 273

1 pharmacists that can custom make medication
2 for them.
3 Q. Okay.
4 A. And they're sold in very tiny
5 quantities.
6 Q. And does the compounding
7 pharmacy have a -- is it registered with the
8 DEA as such?
9 A. Yes. Yes.
10 Q. Okay. You can set that aside.
11 (Mallinckrodt-Stewart Exhibit
12 37 marked for identification.)
13 QUESTIONS BY MR. GOTTO:
14 Q. Exhibit 37 is a multi-page
15 e-mail string beginning on Bates
16 MNK-T1_0000290621, and it's a series of
17 e-mails concerning a prospective new AT
18 clinic, Sunwest Behavioral, in El Paso,
19 Texas.
20 If you -- if we look back at
21 the first -- the earliest e-mail from Pat
22 Wall on May 14th of 2008 --
23 A. Uh-huh.
24 Q. -- Pat says, "David Magno just
25 called customer service. He said that you

Page 274

1 told him to call customer service to obtain
 2 new customer account forms for his addiction
 3 treatment clinic, Sunwest Behavioral Health
 4 Organization," with a phone number and a fax.
 5 "I have faxed him the two new account
 6 applications and explained that we would need
 7 a current DEA license specific to this
 8 clinic. He said that he did not currently,
 9 nor ever in the past, have a clinic account
 10 with us, although he said this is an
 11 existing, not a new, clinic. Have you
 12 visited this clinic?"
 13 And that -- that e-mail was
 14 addressed to Peter Romer.
 15 Do you know who Peter Romer
 16 was?
 17 A. I'm not positive.
 18 Q. Okay. You received a copy of
 19 that e-mail and forwarded it to Mr. Ratliff
 20 and Ms. Harper asking would they consider
 21 this peculiar, correct?
 22 A. Correct.
 23 Q. And what is it about it that
 24 caused you to seek their input as to whether
 25 they considered it peculiar?

Page 275

1 A. Well, based on the content of
 2 my e-mail to Bill and Karen, I had overheard
 3 part of the conversation Pat had with the
 4 customer, and he did not seem to understand
 5 the regulations as far as DEA compliance were
 6 concerned.
 7 Q. Okay. And the next e-mail
 8 Mr. Ratliff responds, saying, "This could
 9 rise to the level of peculiar. Sunrise --
 10 Sunwest has a nice web page. It states
 11 they're accredited by the El Paso Mental
 12 Health and Mental Retardation provider
 13 network. It turns out that the Texas State
 14 Health Services Department is investigating
 15 the relationship between the El Paso Mental
 16 Health and Mental Retardation -- received
 17 state funds and a subsidiary, Sun City
 18 Behavioral Health Care."
 19 In the following paragraph he
 20 says, "Sunwest could well be legitimate, but
 21 I would like to know how long they have been
 22 in existence and their reason for coming to
 23 us."
 24 And then you respond by asking,
 25 "It is my next step to see if the sales rep

Page 276

1 who supports them, Pete Romer, can answer
 2 these questions."
 3 Do you see that?
 4 A. Uh-huh.
 5 Q. Does that refresh your
 6 recollection as to who Mr. Romer was?
 7 A. Yeah.
 8 Q. Okay. And Mr. Ratliff tells
 9 you, yes, and that he's continuing to look at
 10 federal government funding, correct?
 11 A. Uh-huh.
 12 Q. You then, on May 14th, sent an
 13 e-mail to Pete Romer saying that "we'd like
 14 you to see if you can obtain additional
 15 information with respect to how long Sunwest
 16 has been in business and their reason for
 17 coming to Mallinckrodt," correct?
 18 A. Uh-huh.
 19 Q. And then Mr. Romer responded to
 20 you on May -- on May 14th, approximately --
 21 well, less than an hour later, correct?
 22 A. Yes.
 23 Q. And you forwarded that
 24 information ultimately to Mr. Ratliff, who
 25 forward -- sent an e-mail to Ms. Harper

Page 277

1 saying, "Determination made, the account is
 2 not peculiar or suspicious based on
 3 information supplied by the salesman,"
 4 correct?
 5 A. Correct.
 6 Q. And do you have any independent
 7 recollection of any of these communications
 8 other than what's reflected in these e-mails?
 9 A. No.
 10 Q. Okay. And do you know if
 11 ultimately Sunwest Behavioral became a
 12 customer of Mallinckrodt?
 13 A. I don't recall.
 14 Q. Okay. You can set that aside.
 15 (Mallinckrodt-Stewart Exhibit
 16 38 marked for identification.)
 17 QUESTIONS BY MR. GOTTO:
 18 Q. Exhibit 38 is a four-page
 19 e-mail thread beginning at MNK-T1_0002908302,
 20 and the e-mails concerns Gramercy Park
 21 Medical.
 22 Do you have any recollection of
 23 Gramercy Park Medical?
 24 A. No.
 25 Q. If we look on the e-mail -- the

Page 278

1 earliest e-mail on the third page of the
2 exhibit, from Connie Gregory to Brenda
3 Rehkop, copied to you and Susan Marlatt --
4 A. Uh-huh.
5 Q. -- and Mike Perry.
6 First of all, who was Connie
7 Gregory?
8 A. I don't recall.
9 Q. Okay. Do you recall who Susan
10 Marlatt was?
11 A. Yes.
12 Q. Who was that?
13 A. She worked in -- it was either
14 finance or customer data integrity.
15 Q. Okay. How about Mike Perry?
16 A. I don't recall Mike Perry.
17 Q. Okay. Connie Gregory says,
18 "FYI, have left another message for Raymond
19 on his cell to call. We informed him account
20 was still on hold, and the amount past due is
21 now" -- and there's a dollar amount. Seems
22 perhaps to be blurred a little where the
23 comma is located.
24 A. Yeah.
25 Q. "Dates back to January. Unable

Page 279

1 to leave message at clinic office since
2 mailbox is full and he just stepped out."
3 You forwarded that e-mail to
4 Ms. Harper. "Help. Give me some guidance.
5 Do you want information like this for
6 evaluation as well?"
7 What did you mean by that?
8 A. For evaluation with respect to
9 suspicious order monitoring.
10 Q. I see.
11 As compared to simply credit?
12 A. Correct.
13 Q. Okay.
14 A. Yes.
15 Q. All right. And Ms. Harper
16 responds that she -- she did want that
17 information --
18 A. Uh-huh.
19 Q. -- correct?
20 And Ms. Marlatt then responds
21 by noting that some cash poor methadone
22 clinics have some problems paying their
23 bills?
24 A. Yes. Yes.
25 Q. And Mr. Ratliff, on the first

Page 280

1 page of the exhibit, says, "Susan, thank you
2 for your insight; however, being unable to
3 contact them for six months and the product
4 being methadone, in our opinion, would place
5 it in the suspicious category."
6 And did you agree with that?
7 A. Yes.
8 Q. And then Ms. Harper asks Robert
9 Lesnak and Mike Neely for their input
10 regarding the status of Gramercy Park and
11 their perspective on credit issues and
12 whether the customer activity is suspicious,
13 correct?
14 A. Correct.
15 MR. DAVISON: Objection to
16 form.
17 QUESTIONS BY MR. GOTTO:
18 Q. Who was Robert Lesnak?
19 A. I think he was one of the sales
20 reps for the methadone business.
21 Q. And how about Mike Neely?
22 A. Mike Neely was kind of the
23 director of the methadone business.
24 Q. Okay. So as of June 3, Mr. --
25 Mr. Ratliff had already indicated in his --

Page 281

1 in his view, the order was suspicious,
2 correct?
3 A. Correct.
4 Q. And is there a reason to -- for
5 Ms. Harper to then have gotten further input
6 from Mr. Lesnak or Mr. Neely on that topic?
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: I would be
10 speculating.
11 QUESTIONS BY MR. GOTTO:
12 Q. Would you view that as unusual?
13 MR. DAVISON: Objection to
14 form.
15 THE WITNESS: I don't know.
16 QUESTIONS BY MR. GOTTO:
17 Q. Okay. You can set that aside.
18 (Mallinckrodt-Stewart Exhibit
19 39 marked for identification.)
20 QUESTIONS BY MR. GOTTO:
21 Q. Exhibit 39 is a single-page
22 series of e-mails bearing Bates
23 MNK-T1_0003027927.
24 And direct your attention to --
25 it appears to be e-mails regarding the

Page 282

1 results of the FedEx weekly investigation
2 report.
3 Was that a report that you had
4 familiarity with?
5 A. I don't recall.
6 Q. Okay. Well, on August 19 you
7 sent to Lance Frutiger and Philip Wolf an
8 e-mail. "I have a question. What qualifies
9 as an incorrect signature? Does it actually
10 validate that it's really my signature, or
11 does it just validate that it's my name and
12 anyone could have signed it?"
13 Correct?
14 A. Correct.
15 Q. And who were Lance Frutiger and
16 Philip Wolf?
17 A. They both work in
18 transportation at the time, so they oversaw
19 the FedEx and UPS accounts.
20 Q. Okay. And Mr. Frutiger
21 responded to you, "I don't believe the
22 couriers actually ask for ID when they get a
23 signature."
24 And then you forwarded that to
25 Ms. Harper asking, "Is this an acceptable

Page 283

1 practice if what Lance is saying is true?"
2 Correct?
3 MR. DAVISON: Objection to
4 form.
5 THE WITNESS: Correct.
6 QUESTIONS BY MR. GOTTO:
7 Q. So the concern here is that
8 someone at a clinic could sign for a package
9 and not really be the right person?
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: Correct.
13 QUESTIONS BY MR. GOTTO:
14 Q. Do you recall what
15 Ms. Harper -- what, if any, response you
16 received from Ms. Harper on this?
17 A. No, I don't remember.
18 Q. Do you recall if there were
19 ever any safeguards put into place that you
20 were aware of to address the concern that an
21 improper person might sign for a narcotics
22 delivery?
23 A. I'd be speculating. I don't
24 know.
25 Q. Okay. You can set that aside.

Page 284

1 (Mallinckrodt-Stewart Exhibit
2 40 marked for identification.)
3 QUESTIONS BY MR. GOTTO:
4 Q. Exhibit 40 is an e-mail with
5 attachments beginning on Bates
6 MNK-T1_0000449552. And the e-mail is from
7 Sara Heideman to yourself and Charity Aranda.
8 Who was Sara Heideman, if you
9 recall?
10 A. I remember Sara, but I don't
11 remember what department she worked in. She
12 may have been like a data analyst in the
13 marketing department, but I'm not positive.
14 Q. Okay. In any event, the
15 e-mail, which is dated May -- February 17,
16 2009, the subject is ABC cancellation
17 analysis.
18 The e-mail says, "Charity and I
19 have just finished look at the ABC orders,
20 and we found three SKUs in which ABC had
21 significantly overordered over the last
22 couple of weeks. We have looked at the
23 individual DCs normalized monthly demand,
24 September through November of '08, and have
25 left open for each DC approximately

Page 285

1 1.5 months of that quantity, and we propose
2 to approach ABC to cancel of excess orders
3 completely. The total dollar impact of
4 canceling these orders is \$6.1 million."
5 Correct?
6 A. Correct.
7 Q. So do you know what
8 Ms. Heideman meant by -- when she said that
9 ABC had "significantly overordered" over the
10 last couple of weeks?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: I'd be
14 speculating. I believe this is
15 because of the oxycodone shortage, and
16 they were trying to hurry up and be
17 the first in line.
18 QUESTIONS BY MR. GOTTO:
19 Q. Well, did you have an
20 understanding when you received this e-mail
21 as to what overordered meant?
22 MR. DAVISON: Objection to
23 form.
24 THE WITNESS: No.
25

Page 286

1 QUESTIONS BY MR. GOTTO:
2 Q. Do you know if it meant ordered
3 in excess of what the form 222 provided for?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: I'm speculating,
7 but I think it would be in excess of
8 what their prior orders had been.
9 QUESTIONS BY MR. GOTTO:
10 Q. Okay. But these were orders
11 that had already been filled, correct?
12 MR. DAVISON: Objection to
13 form.
14 THE WITNESS: No. I believe
15 these were orders that were open and
16 have left open for each DC.
17 QUESTIONS BY MR. GOTTO:
18 Q. And DC means?
19 A. Distribution center.
20 Q. Okay. The e-mail goes on to
21 say, "These orders are shown in the attached
22 spreadsheet as well as a summary tab for each
23 of the SKUs. I am thinking that we may want
24 to involve Steve Becker on this one since is
25 involves a significant overordering across

Page 287

1 all of the DCs and multiple SKUs."
2 Who was Steve Becker?
3 A. I don't recall.
4 Q. Do you have any recollection of
5 the circumstances that are addressed in this
6 e-mail with the attachment?
7 A. Not positively, no.
8 Q. Okay. You can set that aside.
9 MR. DAVISON: We've been going
10 for about an hour. Do you want to
11 take a break?
12 MR. GOTTO: Okay. We can go
13 off the record.
14 VIDEOGRAPHER: We're going off
15 the record at 4 p.m.
16 (Off the record at 4:00 p.m.)
17 VIDEOGRAPHER: We are back on
18 the record at 4:16 p.m.
19 (Mallinckrodt-Stewart Exhibit
20 41 marked for identification.)
21 QUESTIONS BY MR. GOTTO:
22 Q. Ms. Stewart, Exhibit 41 is a
23 one-page e-mail bearing Bates
24 MNK-T1_0003037286. It's an e-mail from you
25 to Karen Harper concerning a fentanyl order

Page 288

1 from Watson.
2 Do you recall the order that's
3 referenced in this e-mail?
4 A. I do not.
5 Q. Okay. The e-mail says that
6 "Paul from Watson called. Wanted to place an
7 order for 8 kilograms of fentanyl and bring
8 it in on a research license because they were
9 out of quota. They wanted to do this so
10 after January 1st when they had their 2010
11 quota, they could then transfer the material
12 to their manufacturing license, if that's
13 even possible. They were informed that we
14 would not accept this order, adding that an
15 order for that quantity of fentanyl would
16 have to be brought in on a manufacturer's
17 license with a 222 form in support of the
18 purchase. Paul was going to check with his
19 compliance person. Was told that he could do
20 so; however, under our guidelines the order
21 would likely not be accepted unless he agreed
22 to send a letter stating that the material
23 would not be used for the manufacture of
24 product."
25 Did I read that correctly?

Page 289

1 A. You did.
2 Q. Okay. Do you -- do you recall
3 there being any circumstances in which an
4 order was received from a -- from a
5 manufacturer out of quota in which that
6 manufacturer was permitted to buy under a
7 research license -- a research registration
8 with a letter stating that the material would
9 not be used for the manufacture of product?
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: No, I do not.
13 QUESTIONS BY MR. GOTTO:
14 Q. Do you know if this order was
15 filled?
16 MR. DAVISON: Objection. Form.
17 THE WITNESS: I don't know.
18 QUESTIONS BY MR. GOTTO:
19 Q. Okay. You can set that aside.
20 (Mallinckrodt-Stewart Exhibit
21 42 marked for identification.)
22 QUESTIONS BY MR. GOTTO:
23 Q. Exhibit 42 is a two-page e-mail
24 thread beginning at Bates MNK-T1_0003025905.
25 And if you look at the initial

Page 290

1 e-mail, which is at the bottom -- begins at
 2 the bottom of the first page, it's from a Tim
 3 Gray at SJ Investments asking for pricing on
 4 1 kilogram of fentanyl, correct?
 5 A. Yes.
 6 Q. Okay. And that e-mail
 7 ultimately was forwarded to you by Camille
 8 Pokorny --
 9 A. Uh-huh.
 10 Q. -- stating, "Cathy, not sure
 11 how to handle. How are we checking out
 12 customers that are new or old that need to be
 13 reactivated? This customer is wanting to
 14 purchase fentanyl citrate, 1 kilogram.
 15 They're located in Baltimore, Maryland."
 16 You respond, asking what the
 17 name of the company is. "I think it's a
 18 little suspicious to get a message about this
 19 product from an iPhone under the
 20 circumstances, and I'm also suspicious about
 21 the company name, SJ Investments. Doesn't
 22 sound like a pharma company to me. If that's
 23 who's requesting the quote, just confirm that
 24 for me and I'll check into them."
 25 And then you e-mailed Karen

Page 291

1 Harper to say you're suspect and don't know
 2 that you want to sell a kilogram of fentanyl
 3 to an investment company.
 4 Do you see that?
 5 A. Yes.
 6 Q. Do you know if this order was
 7 filled?
 8 A. No, I do not.
 9 Q. Any recollection of
 10 SJ Investments attempting to place an order
 11 for fentanyl?
 12 A. No.
 13 Q. Okay. You can set that aside.
 14 (Mallinckrodt-Stewart Exhibit
 15 43 marked for identification.)
 16 QUESTIONS BY MR. GOTTO:
 17 Q. Exhibit 43 is a one-page e-mail
 18 bearing Bates MNK-T1_0000968496, an e-mail
 19 from you to Charity Aranda, subject Sunrise
 20 chargebacks. And you say, "Charity, here is
 21 the chargeback file I used."
 22 I think you testified a little
 23 earlier today regarding looking at chargeback
 24 data with respect to a customer.
 25 Does this refresh your

Page 292

1 recollection as to whether that customer was
 2 Sunrise?
 3 A. No, it does not.
 4 Q. Okay. Do you think it -- could
 5 this be a second example of your use of
 6 chargeback data?
 7 MR. DAVISON: Objection to
 8 form.
 9 THE WITNESS: I'd be
 10 speculating.
 11 QUESTIONS BY MR. GOTTO:
 12 Q. But in any event, you did use
 13 chargeback data in this example, correct?
 14 A. Correct.
 15 Q. Okay. Do you recall the
 16 purpose you used it for?
 17 A. No, I don't.
 18 Q. Okay. All right. You can set
 19 that aside.
 20 (Mallinckrodt-Stewart Exhibit
 21 44 marked for identification.)
 22 QUESTIONS BY MR. GOTTO:
 23 Q. Exhibit 44 is a two-page e-mail
 24 thread beginning at Bates MNK-T1_0003028219.
 25 And the subject matter of the e-mail is

Page 293

1 Sunrise Wholesale.
 2 Do you see that?
 3 A. Yes.
 4 Q. And the bottom of the first
 5 page there's an e-mail from Ms. Rehkop to
 6 Victor Borelli, copied to you, indicating
 7 that Sunrise has sent in three 222 forms this
 8 week for C-II products.
 9 Second paragraph says, "The 222
 10 forms total \$195,000. I have put the latest
 11 and largest order on hold. It is also
 12 waiting to be allocated until I hear from
 13 you. Were you expecting Sunrise to place
 14 such a large order, two question marks, and
 15 do they really want 2,520 bottles of
 16 oxycodone HCL 30-milligram tabs USP, 100
 17 count each, two question marks?"
 18 You were copied on that e-mail.
 19 You forwarded it to Ms. Harper and
 20 Mr. Ratliff, copying Ms. Rehkop, stating,
 21 "FYI, this is a new customer."
 22 You then forwarded the e-mail
 23 to -- to -- again to Mr. Ratliff and
 24 Ms. Harper, stating that "FYI, the customer
 25 service reps all state that Victor will tell

Page 294

1 them anything they want to hear just so he
2 can get the sale."
3 Do you recall reporting that to
4 Mr. Ratliff and Ms. Harper?
5 A. No.
6 Q. Okay. Do you recall hearing
7 that from customer service reps, that
8 Mr. Borelli would tell them anything they
9 want to hear just to get the sale?
10 A. Yes.
11 Q. And who can you recall hearing
12 that from?
13 A. I don't remember which customer
14 service rep handled this account.
15 Q. Okay. Did that cause you
16 concern?
17 A. When I state that he'd do
18 anything to get the sale, I didn't -- I only
19 meant that he wanted Hobart to run overtime
20 and get another truck in there and, you know,
21 everybody to jump through hoops to get the
22 order ship confirmed that day. So it was a
23 nuisance, but it wasn't illegal.
24 Q. What you said was that "Victor
25 will tell them anything they want to hear."

Page 295

1 The "them" in that sentence --
2 A. Are the customer service reps.
3 Q. Okay. So the customer service
4 reps were telling that you Mr. Borelli -- or
5 at least one of the customer service reps was
6 telling you that Mr. Borelli would tell the
7 customer service reps anything they wanted to
8 hear --
9 A. Yeah.
10 Q. -- just so he could get the
11 sale?
12 A. Correct.
13 Q. And would that include, for
14 example, if they went to Mr. Borelli to get
15 further information about the customer to
16 evaluate a peculiar order?
17 A. I don't think they would have
18 gone -- they would have -- since it was a new
19 account and we had no historical information,
20 they may have gone to Victor to get
21 additional information on it, but ultimately
22 it would not have been Victor's place to
23 authorize the order for sale -- for shipment.
24 Q. Well, in light of what one or
25 more of the customer service reps had told

Page 296

1 you about Mr. Borelli, would you would have
2 been hesitant to rely on information received
3 from him with respect to an order that had
4 been identified as peculiar for -- out of
5 concern that he would provide information in
6 support of the order, perhaps unreliably?
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: No, because he
10 would have -- his boss and others in
11 his organization would have been
12 familiar with the new account.
13 There were steps he had to go
14 through to establish the new customer,
15 so he probably -- and it's
16 speculation -- validated and vetted
17 the information with his boss and
18 others in the customer data integrity
19 group, and it was found to be
20 legitimate enough to set up the new
21 account.
22 QUESTIONS BY MR. GOTTO:
23 Q. So the -- the report you
24 received from one or more customer service
25 reps that you're referring to in your e-mail

Page 297

1 that you send to Mr. Ratliff and Ms. Harper,
2 was that -- were those reports solely in the
3 context of the Sunrise Wholesale account?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: I don't recall.
7 QUESTIONS BY MR. GOTTO:
8 Q. Do you recall -- I mean, in
9 your e-mail you stated in the plural that
10 "the customer service reps all state."
11 A. Uh-huh.
12 Q. This makes it sound like you'd
13 received more than one such report.
14 A. Probably. But Victor had
15 multiple customers, they all had territories,
16 so it wasn't just this customer that they
17 dealt with. So the customer service reps
18 were probably complaining about him trying to
19 push multiple customer orders through over
20 the course of the month or six months or
21 whatever.
22 Q. Okay. And that would likely be
23 orders that involved -- that were not limited
24 to just Sunrise Wholesale?
25 A. Correct.

Page 298

1 Q. Okay. Did you hear back from
2 Mr. Ratliff or Ms. Harper on -- in response
3 to your e-mail concerning Mr. Borelli?
4 A. I don't recall.
5 Q. Now, you had sent your May 20th
6 e-mail at 12:15 p.m., and then the e-mail
7 concerning Mr. Borelli is sent --
8 A. About eight o'clock at night.
9 Q. -- about -- better than seven
10 and a half hours later, right?
11 So apparently it was something
12 that was on your mind late, you know, that
13 evening --
14 A. Uh-huh.
15 MR. DAVISON: Objection.
16 QUESTIONS BY MR. GOTTO:
17 Q. -- on that topic.
18 Do you recall what it was that
19 triggered you to go back and say, well, let
20 me send a follow-up e-mail to Mr. Ratliff and
21 Ms. Harper on this topic?
22 A. No, I don't recall.
23 Q. And again, you don't recall
24 receiving a response from them on it?
25 A. No.

Page 299

1 Q. Okay. You can set that aside.
2 (Mallinckrodt-Stewart Exhibit
3 45 marked for identification.)
4 QUESTIONS BY MR. GOTTO:
5 Q. Exhibit 45 is a three-page
6 document, series of e-mails beginning at
7 Bates MNK-T1_0000290601. And these are also
8 e-mails concerning Sunrise Wholesale from May
9 of 2008.
10 And it appears that -- these
11 e-mails, this was at the time when Sunrise
12 Wholesale was a new -- potential new account,
13 correct?
14 A. Uh-huh.
15 Q. And on the bottom of the second
16 page onto the third page of the exhibit is
17 the e-mail from Ms. Rehkop to Mr. Borelli
18 that we looked at in the prior exhibit where
19 she talks about the multiple 222 forms and
20 that they total \$195,000, correct?
21 A. Correct.
22 Q. In response, Mr. Borelli asks,
23 "What credit level did they receive?"
24 A. Uh-huh.
25 Q. And ultimately Rhonda Hart, on

Page 300

1 the first page of the exhibit, responds to
2 that that "their credit limit is \$35,000. If
3 the order is \$195,000, it will need approval
4 from upper management before it can be
5 released."
6 Do you see that?
7 A. Yes.
8 Q. Okay. And Mr. Ratliff, in the
9 first e-mail -- well, the top e-mail on the
10 first page, says to Ms. Harper, "This seems
11 to be a lot of product for the first order,
12 especially in light of the new customer
13 status and credit limit. Do you know if they
14 completed the D&B?"
15 Do you see that?
16 A. Uh-huh.
17 Q. And the D&B would be a Dun &
18 Bradstreet report?
19 A. Dun & -- yes.
20 Q. And so that would basically be
21 a -- sort of a credit report type thing,
22 correct?
23 A. Correct.
24 Q. Okay. Do you know what the
25 status was -- ultimately, was this order

Page 301

1 filled?
2 A. I don't know.
3 Q. Okay. You can set that aside.
4 (Mallinckrodt-Stewart Exhibit
5 46 marked for identification.)
6 QUESTIONS BY MR. GOTTO:
7 Q. Exhibit 46 is a two-page
8 document, a series of e-mails beginning at
9 MNK-T1_0000307120, and these also concern
10 Sunrise.
11 If you look at the earliest
12 e-mail on the second page from Mr. Borelli to
13 Kate Muhlenkamp, it indicates that Sunrise
14 has been growing in sales each month and that
15 beginning in -- well, the e-mail stated
16 November of 2008, and states that "beginning
17 in January, we can raise our projections for
18 Sunrise to 3,000 bottles monthly of oxy
19 15-milligram and 12,000 bottles of
20 oxy 30-milligram."
21 Correct?
22 A. Correct.
23 Q. And then Mr. Adams forwarded
24 that e-mail to you saying, "For the
25 suspicious order monitoring, this is a

Page 302

1 potential increase on the horizon."
2 A. Correct.
3 Q. Do you recall receiving that?
4 A. No.
5 Q. Okay. When you received that
6 e-mail from Mr. Adams, at that point what
7 steps would you have taken to respond to that
8 piece of information?
9 MR. DAVISON: Objection to
10 form.
11 THE WITNESS: Just what I did.
12 I forwarded on to Karen Harper.
13 QUESTIONS BY MR. GOTTO:
14 Q. Okay.
15 A. And Karen to Bill --
16 Q. Okay.
17 A. -- Ratliff. So that was our
18 protocol.
19 Q. Okay. And do you know if, in
20 fact, increases in Sunrise's order size of
21 the type Mr. Borelli was projecting were
22 received?
23 A. I don't know.
24 Q. Okay. You can set that aside.
25 (Mallinckrodt-Stewart Exhibit

Page 303

1 47 marked for identification.)
2 QUESTIONS BY MR. GOTTO:
3 Q. Exhibit 47 is a single-page
4 series of e-mails bearing Bates
5 MNK-T1_0000418851.
6 And the first e-mail on the
7 bottom half of the page is an e-mail from
8 Mr. Ratliff to a number of individuals
9 discussing an audit of Sunrise distributors.
10 Do you see that?
11 A. Correct.
12 Q. And do you recall this audit
13 occurring?
14 A. I don't recall. I don't
15 believe I attended.
16 Q. Okay. So Mr. Ratliff says,
17 "Karen and Cathy will complete a customer
18 checklist and develop logical questions and
19 areas for the audit."
20 Do you recall doing that?
21 A. No.
22 Q. And then a little later on it
23 says, "An audit report will be generated by
24 Cathy/Karen."
25 Do you recall participating in

Page 304

1 that process?
2 A. No.
3 Q. Okay. Mr. Adams sends -- at
4 the top e-mail on the page, the e-mail from
5 Mr. Adams to Mr. Gunning, saying, "As part of
6 the investigation into oxy use in Florida, an
7 audit of Sunrise is part of the due
8 diligence. The assumption is they are doing
9 everything above board and no issues, but
10 DEA, when alerted to the suspicious order
11 monitoring red flag, indicated it would be a
12 good idea to have an audit."
13 Do you know what the suspicious
14 order monitoring red flag is that Mr. Adams
15 is referring to there?
16 MR. DAVISON: Objection to
17 form.
18 THE WITNESS: No, I don't.
19 QUESTIONS BY MR. GOTTO:
20 Q. And do you have any
21 recollection of the outcome of this audit?
22 A. No, I don't.
23 Q. All right. You can set that
24 aside.
25 (Mallinckrodt-Stewart Exhibit

Page 305

1 48 marked for identification.)
2 QUESTIONS BY MR. GOTTO:
3 Q. Exhibit 48 is a single-page
4 e-mail bearing Bates MNK-T1_0000290065, and
5 it's an e-mail from yourself to Ms. Harper,
6 Mr. Ratliff, copying a number of individuals,
7 concerning Sunrise chargeback summary.
8 And the body of the e-mail
9 says, "Please review the attached summary
10 worksheet. I took the chargeback file
11 marketing provided and removed pharmacies.
12 Then I removed purchases of methadone and
13 various other materials."
14 Next paragraph says, "I tried
15 to identify all the duplicate accounts, first
16 name/last name, last name/first name, and
17 merged the associated data together."
18 Do you recall performing this
19 analysis?
20 A. No, I don't.
21 Q. As you look at it today, do you
22 know what the purpose of the analysis would
23 have been?
24 MR. DAVISON: Objection to
25 form.

Page 306

1 THE WITNESS: No, it would be
2 speculation.
3 QUESTIONS BY MR. GOTTO:
4 Q. Do you recall why you used
5 chargeback data to conduct this analysis?
6 MR. DAVISON: Objection to
7 form.
8 THE WITNESS: I don't recall.
9 QUESTIONS BY MR. GOTTO:
10 Q. Do you recall performing a
11 similar analysis with respect to any other
12 customers?
13 A. No.
14 Q. Do you recall if there was any
15 follow-up that anyone who received this
16 analysis from you requested?
17 MR. DAVISON: Objection to
18 form.
19 THE WITNESS: I'm not aware of
20 any, but I don't recall.
21 QUESTIONS BY MR. GOTTO:
22 Q. Okay. All right. You can set
23 that aside.
24 (Mallinckrodt-Stewart Exhibit
25 49 marked for identification.)

Page 307

1 QUESTIONS BY MR. GOTTO:
2 Q. Exhibit 49 is a multi-page
3 PowerPoint presentation beginning with Bates
4 MNK-T1_0000304563. It's entitled
5 "Mallinckrodt Controlled Substance Suspicious
6 Order Monitoring Program, Introductory
7 Training for Field Sales, June 5, 2008."
8 Do you recall participating in
9 the preparation of any aspect of this
10 presentation?
11 A. No, I do not.
12 Q. Do you recall presenting any
13 training to any Mallinckrodt employees on the
14 suspicious order monitoring program?
15 A. Not to the sales reps.
16 Q. Okay. Who do you recall
17 presenting it to?
18 A. The -- well, not the dosage
19 sales reps. I did do some training for the
20 API sales team.
21 Q. Okay. And did you employ a
22 PowerPoint deck --
23 A. I did.
24 Q. -- similar to Exhibit 49?
25 A. Yes, most likely.

Page 308

1 Q. Okay. And were there -- were
2 there sale -- I'm sorry. Were there training
3 presentations made to various groups at
4 Mallinckrodt on the suspicious order
5 monitoring program from time to time?
6 A. I don't know. I don't recall.
7 Q. In any event, the only one you
8 can recall participating in is the one
9 involving the API sales reps?
10 A. The API sales, uh-huh.
11 Q. Okay. What was the purpose of
12 that training?
13 A. To make sure they understand --
14 understood what we were doing, why we were
15 doing it, and the ramifications if they were
16 anticipating a sale and it didn't come to
17 fruition because the order had been placed on
18 hold for some reason. We wanted to let them
19 know that that was a possibility.
20 Q. And do you recall the
21 approximate time frame of when you conducted
22 that training?
23 A. No. I remember it was in
24 Chicago, but I don't remember the time frame.
25 (Mallinckrodt-Stewart Exhibit

Page 309

1 50 marked for identification.)
2 QUESTIONS BY MR. GOTTO:
3 Q. Exhibit 50 is a single-page
4 document, series of e-mails bearing Bates
5 MNK-T1_0002052682. The first e-mail, dated
6 September 17, 2009, from you to Karen Harper,
7 asks Ms. Harper to review and make
8 appropriate revisions to the attached draft.
9 Ms. Harper responds that "the
10 presentation looks great. New slides on DEA
11 regulatory action taken with Masters and
12 suspicious order monitoring. FAQ and
13 checklist are very good."
14 Does this e-mail relate to
15 modifications you made to a presentation to
16 be -- to be made as part of the training that
17 you conducted?
18 A. Not the training I conducted.
19 Q. What was it concerning?
20 A. This was for training that was
21 going to be conducted by Carla Johnson to the
22 generic -- dosage generic sales meeting.
23 Q. Okay. Training on the -- on
24 the suspicious order --
25 A. On the suspicious order

Page 310

1 monitoring program.
 2 Q. Okay. Great.
 3 And so this is in September of
 4 '09.
 5 Was the training that you
 6 conducted as to the API salespeople, was it
 7 before this? Do you know?
 8 A. I don't recall.
 9 Q. Okay. Okay. You can set that
 10 aside.
 11 (Mallinckrodt-Stewart Exhibit
 12 51 marked for identification.)
 13 QUESTIONS BY MR. GOTTO:
 14 Q. Exhibit 51 is a single --
 15 single-page document containing e-mails from
 16 September 2008 bearing MNK-T1_0000564481.
 17 The primary e-mail is from
 18 Ms. Muhlenkamp to yourself copying
 19 Mr. Gunning concerning an oxycodone Walmart
 20 shipment.
 21 Do you see that?
 22 A. Yes, I do.
 23 Q. Do you recall the circumstances
 24 that are discussed in Ms. Muhlenkamp's
 25 e-mail?

Page 311

1 A. No.
 2 Q. Okay. She indicates that she
 3 was "reviewing orders that were shipped out,
 4 parens, impromptu for this month of
 5 September, and I noticed that the shipments
 6 that actually went out did not tie to what I
 7 had on my allocation list. We were off by
 8 2,340 bottles."
 9 What is impromptu; do you know?
 10 A. I don't know what her intent
 11 was with that.
 12 Q. Okay. Do you recall this
 13 circumstance, that there was a shipment that
 14 was off by 2,340 bottles?
 15 MR. DAVISON: Objection to
 16 form.
 17 THE WITNESS: No.
 18 QUESTIONS BY MR. GOTTO:
 19 Q. Okay. Okay. You can set that
 20 aside.
 21 (Mallinckrodt-Stewart Exhibit
 22 52 marked for identification.)
 23 QUESTIONS BY MR. GOTTO:
 24 Q. Exhibit 52 is a multi-page
 25 series of e-mails beginning at

Page 312

1 MNK-T1_0003027585, and the subject matter in
 2 the e-mails is methadone order for China,
 3 Colonial Walmart Trailer.
 4 Direct your attention to your
 5 e-mail that's on the -- starts on the bottom
 6 of the third page of the exhibit --
 7 A. Uh-huh.
 8 Q. -- dated March 5th of 2009.
 9 And you say, "A couple weeks
 10 ago we moved about six pallets of 500-gram
 11 methadone bottles to Hobart to make room in
 12 Building 5 until we were ready to ship this
 13 to China. We now have contracts in place,
 14 and this sale can transpire."
 15 In the next paragraph you
 16 describe, "Colonial will drop the Walmart
 17 trailer at security through the night Friday
 18 into early Saturday morning. On the tail of
 19 this truck will be six pallets of methadone
 20 for China."
 21 Do you recall any of these
 22 circumstances of this particular order?
 23 A. No.
 24 Q. You go on to say, "On Saturday
 25 morning, March 7th, John Spatz will notify

Page 313

1 security and the spotter that we are ready to
 2 move this truck from Mallinckrodt's street
 3 opposite Z building to the dock area in
 4 Building 5. The seal will be broken, and the
 5 six pallets of methadone will be offloaded.
 6 The Colonial truck will then be resealed with
 7 the extra seal Hobart will place inside the
 8 trailer after the seal number has been
 9 recorded on the Walmart paperwork and placed
 10 back into the trailer. The spotter will then
 11 move the trailer back to the Mallinckrodt
 12 street location awaiting pickup by Colonial
 13 on Sunday."
 14 Do you recall why you would
 15 have been sending an e-mail with this
 16 detailed information on the logistics of this
 17 shipment?
 18 MR. DAVISON: Objection to
 19 form.
 20 THE WITNESS: Yes, we were
 21 moving product from Hobart back to the
 22 St. Louis plant. Transportation costs
 23 were exorbitant to get a truck into
 24 the Hobart plant, so to avoid getting
 25 a truck for just six pallets, we used

Page 314

1 the Walmart truck because there was a
 2 lot of room on the end.
 3 We put -- we put the methadone
 4 six pallets in the tail, sealed it up,
 5 brought it down to the St. Louis plant
 6 so the methadone could be put back in
 7 the warehouse down there, and then the
 8 truck could be sealed again and picked
 9 up there to take to Walmart.
 10 QUESTIONS BY MR. GOTTO:
 11 Q. Okay. And what aspect of your
 12 job responsibilities did -- touched on
 13 dealing with this kind of shipping logistic?
 14 A. Because of my history with
 15 transportation and the warehouses and that, I
 16 was familiar with who to call and what we
 17 needed to do at the plant from a security
 18 perspective. So I...
 19 Q. Okay. Do you remember who
 20 asked you to get involved in this?
 21 A. No, I don't.
 22 Q. All right. You can set that
 23 aside.
 24 (Mallinckrodt-Stewart Exhibit
 25 53 marked for identification.)

Page 315

1 QUESTIONS BY MR. GOTTO:
 2 Q. Exhibit 53 is a two-page
 3 document bearing Bates MNK-T1_0002906694.
 4 It's an e-mail from you to Karen Harper,
 5 copying Mike Pheney and Penny Myers,
 6 concerning an overshipment of methadone to
 7 Albert Einstein College of Medicine.
 8 Do you recall the circumstances
 9 that are described in your e-mail?
 10 A. No, I don't.
 11 Q. Okay. You indicate in the
 12 e-mail that -- in the first paragraph you
 13 indicate, "This resulted in the violation of
 14 the DEA regulations in that we overshipped
 15 against the 222 form by three bottles."
 16 Correct?
 17 A. Correct.
 18 Q. And in the next to last
 19 paragraph you say, "While it would be far too
 20 complicated to try to explain all the details
 21 in this e-mail. In summary, fulfilment of
 22 the three lines on this 222 form required
 23 four orders and 17 transactions. The forms
 24 and multiple Post-it note instructions became
 25 very confusing and opened us to the potential

Page 316

1 for errors that could ultimately result in
 2 DEA sanctions."
 3 In your next paragraph you say,
 4 "As a result, I would like to revisit our
 5 practice of allowing multiple ship dates on a
 6 single 222 form."
 7 Is that one of the topics you
 8 discussed earlier in terms of clearing the
 9 222 form?
 10 A. With the Kaizen event, yes.
 11 Q. Okay. After the final
 12 shipment?
 13 A. Uh-huh.
 14 Q. And so the problem that's
 15 described in the -- this exhibit, your
 16 January 22, 2009 e-mail, in your view was a
 17 result of clearing the 222 form line by line?
 18 MR. DAVISON: Objection to
 19 form.
 20 THE WITNESS: Correct.
 21 QUESTIONS BY MR. GOTTO:
 22 Q. Okay. You can set that aside.
 23 (Mallinckrodt-Stewart Exhibit
 24 54 marked for identification.)
 25

Page 317

1 QUESTIONS BY MR. GOTTO:
 2 Q. Exhibit 54 is a three-page
 3 document, series of e-mails beginning Bates
 4 MNK-T1_0002906294. The -- if we look back --
 5 if we look at the second page of the exhibit,
 6 there's an e-mail from Karen Harper to you
 7 discussing an AmerisourceBergen shortage
 8 discrepancy of 84 100-count oxycodone
 9 5-milligram tablets, correct?
 10 A. Uh-huh.
 11 Q. And what's meant by a "shortage
 12 discrepancy" in this context?
 13 MR. DAVISON: Objection to
 14 form.
 15 THE WITNESS: I'm assuming it
 16 means that the customer did not
 17 receive the quantity that they
 18 ordered.
 19 QUESTIONS BY MR. GOTTO:
 20 Q. Okay. So they received
 21 84 bottles fewer than they were expecting?
 22 MR. DAVISON: Objection to
 23 form.
 24 QUESTIONS BY MR. GOTTO:
 25 Q. Or that they had ordered?

Page 318

1 A. I'm assuming, yeah.
2 Q. Okay. In your e-mail on the
3 bottom of the first page, March 6th of '09,
4 you say, "This is definitely a process that
5 needs to be refined. I agree there is a lot
6 of opportunity for improvement on the part of
7 the CSRs and the overall process that's been
8 in place to date."
9 Do you recall this circumstance
10 arising back in '09?
11 A. No, I can't.
12 Q. You conclude your e-mail by
13 saying, "Set something up and we can nail it
14 down," which appears to be a discussion you
15 want to have with -- to include Ms. Spalding
16 in, correct?
17 A. Correct.
18 Q. Do you recall if that occurred?
19 A. I don't know.
20 Q. Okay. All right. You can set
21 that aside.
22 (Mallinckrodt-Stewart Exhibit
23 55 marked for identification.)
24 QUESTIONS BY MR. GOTTO:
25 Q. Exhibit 55 is a two-page

Page 319

1 document, series of e-mails, beginning with
2 MNK-T1_0000290570, and it concerns a series
3 of e-mails that concern a robbery that
4 occurred at Aegis Medical Systems.
5 Do you see that?
6 A. Uh-huh.
7 Q. Do you recall that event?
8 A. No, I don't.
9 Q. Do you recall any other
10 robberies or theft of product being reported
11 by any customers --
12 A. No.
13 Q. -- in regards to narcotics?
14 A. No, I have not.
15 Q. All right. You can set that
16 aside.
17 (Mallinckrodt-Stewart Exhibit
18 56 marked for identification.)
19 QUESTIONS BY MR. GOTTO:
20 Q. Exhibit 56 is a single-page
21 e-mail bearing Bates MNK_TNSTA05122094, an
22 e-mail exchange between you and Karen Harper
23 from August of 2011.
24 In her e-mail Ms. Harper says,
25 "On Friday, Mike Santowski told me he had

Page 320

1 gotten directional approval from Tom Berry to
2 add a person for suspicious order monitoring;
3 however, it is shaping up to be a data
4 analyst-type person."
5 Who was Mike Santowski?
6 A. He replaced my former vice
7 president, JoAnne Levy, when she left the
8 company.
9 Q. Okay. And who was Tom Berry?
10 A. I'm not positive. I think he
11 was one of the sales reps on the bulk side of
12 the business.
13 Q. Okay. Had you requested that
14 there be a person added for suspicious order
15 monitoring?
16 A. I don't recall.
17 Q. Okay. Ms. Harper goes on to
18 say, "As a justification process moves
19 forward, I will tell you know if the roles
20 and responsibilities are beefed up to a
21 higher band."
22 Do you know what she meant by
23 that?
24 MR. DAVISON: Objection to
25 form.

Page 321

1 THE WITNESS: Salary band.
2 QUESTIONS BY MR. GOTTO:
3 Q. Okay.
4 "Sorry that this is not in the
5 ballpark for your consideration. I wish it
6 could have worked out because I place a high
7 value the contributions you could potentially
8 make to the program."
9 Is Ms. Harper identifying this
10 as a position that you would likely not be
11 interested in because of the salary level?
12 MR. DAVISON: Objection to
13 form.
14 THE WITNESS: I believe so.
15 QUESTIONS BY MR. GOTTO:
16 Q. Okay. Had you expressed to
17 Ms. Harper an interest in moving to a
18 suspicious order monitoring position?
19 A. I don't recall that
20 specifically.
21 Q. Okay. Had you expressed an
22 interest in changing the -- your job
23 responsibilities at this time frame?
24 A. I don't recall.
25 Q. And you say in response,

Page 322

1 "Thanks for your information. We shall see
2 what lies ahead."
3 Was this about the time you
4 transitioned from customer service to
5 transportation?
6 A. Could have been. Very close.
7 Q. Okay. All right. You can set
8 that aside.
9 MR. GOTTO: Why don't we go off
10 the record for just a couple of
11 minutes. I think there may be just
12 one more thing we want to go over.
13 MR. DAVISON: Okay.
14 VIDEOGRAPHER: We are going off
15 the record at 4:59 p.m.
16 (Off the record at 4:59 p.m.)
17 VIDEOGRAPHER: We are back on
18 the record at 5:01 p.m.
19 (Mallinckrodt-Stewart Exhibit
20 57 marked for identification.)
21 QUESTIONS BY MR. GOTTO:
22 Q. Exhibit 57 is a multi-page
23 document, a series of e-mails, beginning at
24 Bates MNK-T1_0000562682, and it concerns a
25 customer named Masters.

Page 323

1 And if you turn to the one,
2 two, three, fourth page of the exhibit, the
3 next to last page, there's an e-mail from you
4 to Karen Harper on June 3, 2008, indicating
5 "this is a significant increase in volume,
6 ten times. Apparently their other supplier
7 is unable to get product to them."
8 Do you see that?
9 A. Uh-huh.
10 Q. Do you recall this circumstance
11 at all?
12 A. No, I don't.
13 Q. Okay. Ms. Harper responds to
14 you that "if Masters Pharmacy is an existing
15 established account in good standing, and
16 given the valid business reason that the
17 other supplier cannot fulfill orders, there's
18 no opposition from the DEA compliance
19 suspicious order monitoring perspective to
20 servicing the customer."
21 Do you see that?
22 A. Yes.
23 Q. Okay. And on the prior page,
24 your June 3, 2008 e-mail to Kate Muhlenkamp
25 says, "My biggest concern at this point is

Page 324

1 the sheer increase in volumes that they're
2 ordering now."
3 Do you recall having that
4 concern?
5 A. No.
6 Q. Okay. Ms. Muhlenkamp responds
7 to you, "Understood, and we are working
8 through that. They insist that they have the
9 demand and that this was a true shift from
10 Actavis to us as a result of Actavis supply
11 issues."
12 Do you see that?
13 A. Yes, I do.
14 Q. And who was Actavis?
15 A. Actavis was one of our
16 customers.
17 Q. Okay. And so the understanding
18 was that Actavis could not supply this
19 customer, and therefore they came to
20 Mallinckrodt?
21 A. Right.
22 MR. DAVISON: Objection to
23 form.
24 THE WITNESS: Right.
25

Page 325

1 QUESTIONS BY MR. GOTTO:
2 Q. On the first page of the
3 document, there's an e-mail from Mr. Ratliff:
4 "By way of information, Kate, Vic, Karen and
5 I discussed the large increase in volume
6 being generated by Masters Pharmaceutical,
7 Cincinnati, Ohio, as a result in
8 interrupted -- an interrupted supply by
9 another vendor. It was determined that
10 Masters has been a customer for approximately
11 one and one-half years with no issues. They
12 order approximately 91 SKUs from Covidien at
13 any given time. Currently they're ordering
14 approximately 2,000 bottles of oxycodone from
15 us, with a recent order increasing
16 substantially to 24,000 bottles."
17 Do you see that?
18 A. Yes.
19 Q. It goes on to say, "Both Kate
20 and Vic have visited the customer in the last
21 60 days and were able to determine Masters
22 was ordering a large amount from another
23 vendor, much larger than our current level of
24 supply."
25 And do you know who he means by

Page 326

1 "Kate and Vic"?
2 A. Kate Muhlenkamp and Victor
3 Borelli.
4 Q. Okay. "It was determined that
5 Actavis cannot supply customers with
6 oxycodone at this time in the 15- and
7 30-milligram product because of a recall.
8 Supposition would indicate that the other
9 supplier is Actavis, based on their market
10 share."
11 And the top of the page there's
12 an e-mail from Mr. Gunning, "It looks like
13 everyone is okay with Masters," correct?
14 A. (Witness nods head.)
15 Q. And do you know if that was the
16 resolution, that the order would be filled?
17 A. I don't know for sure.
18 Q. Okay. Do you know if there was
19 any effort to contact Actavis to find out if,
20 in fact, they were the supplier and were, in
21 fact, unable to supply Masters with this
22 order?
23 A. I don't know that.
24 Q. Okay. You don't have any
25 information on this beyond what's contained

Page 327

1 in Exhibit 57?
2 A. Correct.
3 Q. Okay. Okay. You can put that
4 aside.
5 MR. GOTTO: And with that, I
6 have no further questions for you.
7 Thank you very much for your time.
8 THE WITNESS: Oh, come on.
9 Thank you.
10 MR. GOTTO: Shall we go off the
11 record for a moment?
12 MR. DAVISON: Let's go off the
13 record for a moment.
14 VIDEOGRAPHER: We are going off
15 the record at 5:05 p.m.
16 (Off the record at 5:05 p.m.)
17 VIDEOGRAPHER: We are back on
18 the record at 5:15 p.m.
19 EXAMINATION
20 QUESTIONS BY MS. HERZFELD:
21 Q. Okay. Good afternoon, or I
22 guess good evening, Ms. Stewart.
23 How are you?
24 A. I'm fine. Thank you.
25 Q. Good. My name is Tricia

Page 328

1 Herzfeld, and I'm an attorney representing
2 the plaintiffs in the Tennessee litigation.
3 A. Okay.
4 Q. Are you familiar with the
5 Tennessee litigation?
6 A. No, not per se.
7 Q. Okay. Have you heard about it
8 at all, that there is Tennessee litigation?
9 A. No.
10 MS. HERZFELD: Okay. Before we
11 get going with my few questions that
12 we have here, my law firm has lodged a
13 standing objection to the cross-notice
14 we've received in all of these cases
15 regarding document production
16 compliance and artificial limitation
17 on the time limitation in order to
18 take questions of the witness. We
19 believe that the Tennessee Rules of
20 Civil Procedure are what should
21 control us in our Tennessee state
22 case.
23 So I'm just putting those
24 objections on the record.
25 MR. DAVISON: And we obviously

Page 329

1 disagree with those objections, so
2 I'll just make that clear on the
3 record as well.
4 MS. HERZFELD: Okay. Great.
5 QUESTIONS BY MS. HERZFELD:
6 Q. Moving along, Ms. Stewart, have
7 you ever been to Tennessee before?
8 A. I have.
9 Q. Okay. When have you been?
10 A. We -- a group of us from
11 Mallinckrodt went to the FedEx hub in Memphis
12 and did an audit to monitor our products,
13 excuse me, coming in on the plane and watch
14 the distribution process until it's loaded on
15 the trucks to go out to the customers.
16 Q. Okay. Great.
17 And what year was that?
18 A. Oh, I don't recall.
19 Q. Do you think it was 2 years
20 ago, 5 years ago, 15 years ago?
21 A. Oh, no. I would say at least
22 six, seven years ago.
23 Q. Okay. And what was your
24 position when you went there?
25 A. I believe it was when I was in

Page 330

1 dosage customer service.
2 Q. Okay. And do you recall who
3 went with you on the trip?
4 A. Jim Champion, I believe Bonita
5 Rohling, and I believe Eileen Spaulding, and
6 then our FedEx reps accompanied us.
7 Q. Okay. And do you know how long
8 you were there? One day? Two days? Four
9 days?
10 A. Oh, one day.
11 Q. One day?
12 A. Yeah. We arrived with the
13 plane at midnight, and once the stuff was
14 distributed and on the trucks, we left.
15 Q. Okay. Did you even stay
16 overnight in Memphis?
17 A. Yes, we did.
18 Q. Okay. Did you get to at least
19 have some barbecue?
20 A. At Rendezvous.
21 Q. Very good. Also my favorite.
22 Very, very good choice.
23 Do you know whose idea it was
24 to go down and have this visit to the FedEx
25 location?

Page 331

1 A. No, I don't.
2 Q. Okay.
3 A. I don't recall.
4 Q. Was it your idea?
5 MR. DAVISON: Objection to
6 form.
7 THE WITNESS: I don't recall.
8 QUESTIONS BY MS. HERZFELD:
9 Q. Okay. And do you know why it
10 is that the trip was warranted?
11 A. Because of the volume of
12 narcotics we shipped with FedEx through that
13 hub, we just wanted to make sure that we
14 understood how they were handling the
15 product.
16 Q. Do you know if there had been a
17 complaint?
18 A. No.
19 Q. Do you know if there was a
20 concern?
21 A. No.
22 Q. Okay. Do you know if there's
23 routine audits of other hubs?
24 A. No. FedEx was the only hub
25 that we audited. All of the Hobart products

Page 332

1 went through that hub.
2 Q. Okay. So all the Hobart
3 products went through that hub.
4 A. Uh-huh.
5 Q. Okay. And was there somebody
6 taking notes during that trip?
7 A. I don't recall.
8 Q. Okay. Did you take notes?
9 A. No.
10 Q. Okay. Okay. And other than
11 that one trip to Memphis where you got to
12 enjoy our lovely Rendezvous ribs, have you
13 been to Tennessee any other time?
14 A. I've been through Tennessee.
15 Q. Okay. In what context?
16 A. Oh, wait, I take that back. I
17 went to Gatlinburg.
18 Q. Oh? Uh-huh? What year?
19 A. 2009, '8, '9.
20 Q. Well before the wildfires?
21 A. Yes. Yes.
22 Q. Okay. And what brought you to
23 Gatlinburg? Were you a tourist?
24 A. Yes.
25 Q. Okay. Have you been to

Page 333

1 Nashville?
2 A. No, not yet.
3 Q. You should come.
4 A. I can't wait.
5 Q. Okay. Great.
6 So other than going to
7 Gatlinburg for tourist activities and Memphis
8 for work and generally driving through
9 Tennessee, have you been to Tennessee any
10 other times?
11 A. Not that I recall.
12 Q. Okay. And when you've driven
13 through, kind of where have you been going
14 from and to?
15 A. From St. Louis through to, I
16 believe it was, Alabama, Orange Beach. And
17 that was probably -- or maybe another time
18 going to Destin.
19 Q. Mostly to go from St. Louis to
20 beaches?
21 A. Yes.
22 Q. Okay. So for pleasure, not for
23 business?
24 A. Correct.
25 Q. Okay. Great.

Page 334

1 Do you have any friends who
 2 live in Tennessee?
 3 A. No.
 4 Q. How about any family members?
 5 A. I have -- not immediate family
 6 members. My grandson has an uncle and aunt
 7 that live there. She works for Caterpillar.
 8 Q. Oh, uh-huh. Okay. Very good.
 9 Caterpillar is one of our big companies in
 10 Tennessee, so we're all very familiar with
 11 them.
 12 You're aware of the opioid
 13 crisis in this country; is that correct?
 14 MR. DAVISON: Objection to
 15 form.
 16 THE WITNESS: Yes.
 17 QUESTIONS BY MS. HERZFELD:
 18 Q. Have you heard that the
 19 Appalachian region of the country has been
 20 particularly hard hit by it?
 21 MR. DAVISON: Objection to
 22 form.
 23 THE WITNESS: No.
 24 QUESTIONS BY MS. HERZFELD:
 25 Q. Okay. You haven't heard that

Page 335

1 it's particularly bad in West Virginia?
 2 MR. DAVISON: Objection to
 3 form.
 4 THE WITNESS: No.
 5 QUESTIONS BY MS. HERZFELD:
 6 Q. How about Kentucky?
 7 MR. DAVISON: Objection to
 8 form.
 9 THE WITNESS: No.
 10 QUESTIONS BY MS. HERZFELD:
 11 Q. Have you ever heard or
 12 discussed with anybody the opioid problem in
 13 Tennessee?
 14 MR. DAVISON: Objection to
 15 form.
 16 THE WITNESS: No.
 17 QUESTIONS BY MS. HERZFELD:
 18 Q. Okay. Have you ever heard of
 19 The Oxy Express?
 20 A. No.
 21 Q. Okay. What about The Blue
 22 Highway?
 23 A. Is that the highway through the
 24 Smokeys? No, I've not -- that's the only --
 25 no.

Page 336

1 Q. Okay. Have you ever heard of
 2 I-75 being a drug trafficking corridor from
 3 Florida to Ohio?
 4 A. No.
 5 Q. Okay. Do you know what I-75
 6 is?
 7 A. No.
 8 Q. Okay. Did you know that
 9 oxycodone was going from Florida to
 10 Tennessee?
 11 MR. DAVISON: Objection to
 12 form.
 13 THE WITNESS: No.
 14 I was going to say, do you mean
 15 illegally?
 16 QUESTIONS BY MS. HERZFELD:
 17 Q. Well, let's start with legally.
 18 Did you know that legally
 19 oxycodone was going from Florida to
 20 Tennessee?
 21 MR. DAVISON: Objection to
 22 form.
 23 THE WITNESS: No.
 24 QUESTIONS BY MS. HERZFELD:
 25 Q. Okay. What about illegally?

Page 337

1 MR. DAVISON: Objection to
 2 form.
 3 THE WITNESS: No.
 4 QUESTIONS BY MS. HERZFELD:
 5 Q. So when I say asked you that
 6 question, you said, "illegally or legally?"
 7 Why did you clarify that way?
 8 A. Well, because traffickers, you
 9 know, we have them that come up Highway 44 in
 10 Missouri, is an avenue, so I don't think any
 11 state is exempt from that.
 12 Q. Okay. And so when you're
 13 saying "traffickers," you mean drug
 14 traffickers?
 15 A. Drug traffickers, yes.
 16 Q. And in Missouri, Highway 44 is
 17 the main thoroughfare for that?
 18 A. Yes.
 19 Q. Okay. And do you know
 20 that sometimes oxycodone, as you all say
 21 it -- right? I'm trying to say it the right
 22 way. I've always said it as oxycodone, but
 23 it seems that you all say it as oxycodone,
 24 right?
 25 A. Oxy for short.

Page 338

1 Q. Oxy for short.
2 You've heard that oxy can be
3 sold on the street illegally; is that right?
4 MR. DAVISON: Objection to
5 form.
6 THE WITNESS: Yes.
7 QUESTIONS BY MS. HERZFELD:
8 Q. Okay. And have you heard
9 anything about oxy illegally being trafficked
10 on Highway 44 in Missouri?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: Illegally? Is
14 that what you said?
15 QUESTIONS BY MS. HERZFELD:
16 Q. Yes.
17 A. Yes.
18 Q. Okay. And when you were
19 working with the suspicious order monitoring
20 team, did you all ever -- did anybody on that
21 team ever have a conversation about taking
22 into account specific high drug abuse areas
23 and making determinations if an order would
24 be suspicious or not?
25 MR. DAVISON: Objection to

Page 339

1 form.
2 THE WITNESS: No.
3 QUESTIONS BY MS. HERZFELD:
4 Q. Okay. Did you have access to
5 that information, to your knowledge?
6 A. No, we did not.
7 Q. Do you know if anybody was
8 charged with looking for statistics or
9 arrests about high drug areas?
10 MR. DAVISON: Objection to
11 form.
12 THE WITNESS: No. We did ask
13 the sales reps when they were
14 establishing a new account to pay
15 attention to the vicinity, the area,
16 that the business was going to be in
17 and to take that into account, but
18 that's all we did.
19 QUESTIONS BY MS. HERZFELD:
20 Q. Okay. And do you know when you
21 asked the sales reps to take that into
22 account if that was ever put down in writing
23 anywhere?
24 A. I don't know for sure.
25 Q. Okay. If I were to try to look

Page 340

1 for it, where would I look?
2 A. There would be some form of a
3 new customer checklist.
4 Q. Okay. Okay. And what about a
5 particular area were the sales reps supposed
6 to look for?
7 MR. DAVISON: Objection to
8 form.
9 THE WITNESS: Just because of
10 the security required to house C --
11 not so much C-Is, because you don't
12 sell many of those, but C-IIs, is it
13 fenced, is it easy to get in and out
14 of, does the physical building have a
15 vault that's sufficient to hold the
16 product, that type of stuff.
17 QUESTIONS BY MS. HERZFELD:
18 Q. What about if the building was
19 in a high crime area?
20 MR. DAVISON: Objection to
21 form.
22 QUESTIONS BY MS. HERZFELD:
23 Q. Is that something that the
24 sales reps were instructed to look for?
25 MR. DAVISON: Same objection.

Page 341

1 THE WITNESS: I can't say per
2 se that they were told specifically to
3 look for that.
4 QUESTIONS BY MS. HERZFELD:
5 Q. Okay. What about statistics
6 for crimes within like the ZIP code of where
7 the location was?
8 A. I don't recall them being told
9 to do that, but that's not to say that they
10 didn't take it upon themselves to perhaps do
11 it.
12 Q. Okay. Do you know if anybody
13 did?
14 MR. DAVISON: Objection to
15 form.
16 THE WITNESS: I don't know.
17 (Mallinckrodt-Stewart Exhibit
18 58 marked for identification.)
19 QUESTIONS BY MS. HERZFELD:
20 Q. Okay. We're going to go
21 through a series of documents here, but
22 hopefully mine will be a little bit quicker.
23 I don't have as many.
24 MS. HERZFELD: And
25 unfortunately they're not stapled.

Page 342

1 I'm sorry, guys, they're just not
 2 stapled.
 3 QUESTIONS BY MS. HERZFELD:
 4 Q. Okay. If you could take a look
 5 at what we have marked as Exhibit 58. Let me
 6 know when you're finished.
 7 Are you finished reviewing it?
 8 A. Yes.
 9 Q. Okay. Great.
 10 Do you recognize this document?
 11 A. Not particularly.
 12 Q. What does it appear to be to
 13 you?
 14 A. It appears to be a document
 15 that I composed to send to my boss about
 16 topics and watch-outs that we might want to
 17 consider as part of the suspicious order
 18 monitoring program.
 19 Q. Okay. And it looks like that
 20 document is attached to an e-mail that you
 21 sent on Monday, May 12th, at 8:50 at night to
 22 Michael Pheney, Bill Ratliff and Karen
 23 Harper; is that right?
 24 A. Correct.
 25 Q. Okay. And did you typically

Page 343

1 work until 8:50 at night?
 2 MR. DAVISON: Objection to
 3 form.
 4 THE WITNESS: Well, many
 5 nights.
 6 QUESTIONS BY MS. HERZFELD:
 7 Q. Okay. And so it says in this
 8 e-mail that you had done some research on the
 9 Internet over the weekend and found some,
 10 quote, "triggers that should send up a flag
 11 on what might constitute a peculiar or
 12 suspicious order."
 13 Did I read that correctly?
 14 A. Yes.
 15 Q. Did somebody ask you to do some
 16 research on things that could be red flags or
 17 triggers, or did you take that upon yourself?
 18 A. No, I took it upon myself.
 19 Q. And why is it that you did
 20 that?
 21 A. Because I wanted to help
 22 develop the most robust program we could.
 23 Q. Okay. And before you made this
 24 list, did you look at all of the DEA guidance
 25 that had been put out in 2006 or 2007?

Page 344

1 MR. DAVISON: Objection to
 2 form.
 3 THE WITNESS: I believe -- I
 4 believe I did.
 5 QUESTIONS BY MS. HERZFELD:
 6 Q. Okay. And do you know what
 7 websites or resources you looked at in order
 8 to compile this list?
 9 A. Oh, I don't -- I don't recall.
 10 Q. Okay. And it looks like some
 11 of these things may have been eventually put
 12 into a procedure at Mallinckrodt and other
 13 things were not.
 14 Do you know which ones were or
 15 weren't?
 16 MR. DAVISON: Objection to
 17 form.
 18 THE WITNESS: No, I don't.
 19 QUESTIONS BY MS. HERZFELD:
 20 Q. Okay. Did you ever have any
 21 conversation with anyone about this document
 22 you put together after you submitted it to
 23 these three individuals?
 24 A. I don't recall.
 25 Q. Okay.

Page 345

1 (Mallinckrodt-Stewart Exhibit
 2 59 marked for identification.)
 3 QUESTIONS BY MS. HERZFELD:
 4 Q. And the next one we're going to
 5 mark as Exhibit 59.
 6 Let me know when you've had an
 7 opportunity to finish reviewing it.
 8 A. Okay. Okay.
 9 Q. Okay. And what does that
 10 document appear to be to you, ma'am?
 11 A. I appeared to be having had a
 12 discussion with the two people or the three
 13 people that are involved in the methadone
 14 business and explaining to them how we want
 15 the sales reps to do more thorough
 16 investigating of the clinics.
 17 They are pushing back, saying
 18 because of the clients' privacy and stuff
 19 like that, that the clinics aren't going to
 20 want us to take photographs and stuff like
 21 that.
 22 Q. Okay. And this all, it looks
 23 like, is the discussion that you summarized
 24 in an e-mail that you sent to Karen Harper
 25 and Bill Ratliff --

Page 346

1 A. Yes.
 2 Q. -- on July 29, 2008; is that
 3 right?
 4 A. Yes.
 5 Q. Okay. And so it does reference
 6 the AT group.
 7 What is the AT group?
 8 A. Addiction therapy.
 9 Q. Okay. And Mike, Penny and Bob,
 10 have we talked about all of them today
 11 already?
 12 A. Mike is Mike Gunning. Penny
 13 is -- I can't remember Penny's last name.
 14 Q. Okay.
 15 A. And I think Bob is Bob Lesnak.
 16 Oh, Penny is Myers.
 17 Q. Okay.
 18 A. She's copied on this e-mail.
 19 Q. Okay. And are they all in the
 20 addiction treatment group?
 21 A. Yes.
 22 Q. Okay. And so they were pushing
 23 back on some of the taking photographs, that
 24 types of thing?
 25 A. Correct.

Page 347

1 MR. DAVISON: Objection to
 2 form.
 3 QUESTIONS BY MS. HERZFELD:
 4 Q. There was a suggestion that
 5 perhaps a new clinic could be serviced for a
 6 period of 30 days with some restrictions for
 7 kind of that investigatory period?
 8 A. Correct. Right. Yes.
 9 Q. Do you know if you ever
 10 received a response to this e-mail?
 11 A. I don't recall.
 12 Q. Do you know if any of those
 13 suggestions were implemented?
 14 A. I don't recall.
 15 (Mallinckrodt-Stewart Exhibit
 16 60 marked for identification.)
 17 QUESTIONS BY MS. HERZFELD:
 18 Q. Okay. Okay. We'll hand you
 19 what we've marked as Exhibit 60.
 20 Okay. And could you identify
 21 this document for me, please?
 22 A. This was an e-mail that I sent
 23 to Erica Abbett -- and I don't remember what
 24 her role was at the time -- and copied the
 25 marketing people and my bosses.

Page 348

1 We received telephone calls
 2 from residents of the state of Florida
 3 essentially claiming price gouging. And
 4 while those weren't complaints that were in
 5 our purview, I was looking for guidance on
 6 where I could direct those people to go to
 7 lodge their complaints within the state.
 8 Q. Okay. So my first question is
 9 it looks like somebody is calling somebody
 10 Kate.
 11 Do you sometimes go by Kate?
 12 A. No. Kate is Kate Muhlenkamp.
 13 Q. Okay. So you always go by
 14 Cathy?
 15 A. Yeah.
 16 Q. Okay. Okay. And this e-mail
 17 exchange, it looks like, was sent
 18 February 25, 2009; is that right?
 19 A. Yes.
 20 Q. Okay. And did you receive the
 21 phone calls from the people in Florida, or
 22 did somebody tell you about them?
 23 MR. DAVISON: Objection to
 24 form.
 25 THE WITNESS: Probably my

Page 349

1 customer service reps received the
 2 calls, and they relayed the
 3 information to me.
 4 QUESTIONS BY MS. HERZFELD:
 5 Q. Okay. And do you know how many
 6 calls there were?
 7 MR. DAVISON: Objection to
 8 form.
 9 THE WITNESS: According to this
 10 there were two, but I don't have a
 11 personal recollection of that.
 12 QUESTIONS BY MS. HERZFELD:
 13 Q. Okay. And so you characterize
 14 this as thinking it was price gouging; is
 15 that right?
 16 A. Yes.
 17 Q. Okay. In looking at it, it
 18 says, "One pharmacy was going to charge
 19 somebody an additional \$400 for his
 20 prescription. The other one said the
 21 pharmacy wasn't accepting his insurance and
 22 increased the price."
 23 A. Yes.
 24 Q. So that could be a price
 25 gouging?

Page 350

1 MR. DAVISON: Objection to
2 form.
3 QUESTIONS BY MS. HERZFELD:
4 Q. Could that also be an indicator
5 that a pharmacy is not on the up and up?
6 MR. DAVISON: Objection to
7 form.
8 THE WITNESS: I -- that would
9 be speculation.
10 QUESTIONS BY MS. HERZFELD:
11 Q. Okay. But do you think it
12 could be?
13 MR. DAVISON: Objection to
14 form.
15 THE WITNESS: I suppose it
16 could be, yes.
17 QUESTIONS BY MS. HERZFELD:
18 Q. Is that something that when you
19 were looking at it as a member of the
20 suspicious order monitoring team that you
21 thought to yourself, "I should maybe look at
22 this in the context of maybe something is up
23 with the pharmacy"?
24 MR. DAVISON: Objection.
25 THE WITNESS: I don't know that

Page 351

1 they were the same pharmacy.
2 QUESTIONS BY MS. HERZFELD:
3 Q. Okay. So you think it might
4 have been --
5 A. Two separate pharmacies.
6 Q. Okay. Do you know if any
7 investigation was done on those pharmacies?
8 MR. DAVISON: Objection.
9 THE WITNESS: I don't know.
10 QUESTIONS BY MS. HERZFELD:
11 Q. Okay. And do you know if
12 you -- if there was any follow up to this
13 e-mail that was sent about this issue?
14 MR. DAVISON: Objection.
15 THE WITNESS: I don't recall.
16 QUESTIONS BY MS. HERZFELD:
17 Q. Okay. Great. Thank you very
18 much.
19 (Mallinckrodt-Stewart Exhibit
20 61 marked for identification.)
21 QUESTIONS BY MS. HERZFELD:
22 Q. They'll start from the back.
23 Okay. I've handed you what we have marked as
24 Plaintiff's Exhibit 61.
25 If you flip with me to the

Page 352

1 second to last page --
2 A. Uh-huh.
3 Q. The last page seems to have
4 nothing on it, so the second to last page.
5 There is the e-mail exchange
6 that starts from Christie Kegg to a whole
7 bunch of people, April 15, 2009, at 7:32 a.m.
8 Do you see where I am?
9 A. Yes.
10 Q. Okay. And it says, "All,
11 please review today's Federal Register
12 Notices. Thank you, Christie."
13 Do you know what a Federal
14 Register Notice is?
15 A. Yes. They're published daily,
16 and any changes the government is making to
17 any of the Code of Federal Regulations,
18 whether it be 21 CFR, which pertains to this
19 business, or any of the others -- there's
20 multiple codes of federal regulation -- it's
21 published in the Federal Register Notice. So
22 we had people in Karen's group that just read
23 them every day and let us know about issues
24 like this.
25 Q. Okay. And so that e-mail we

Page 353

1 were talking about, the 7:32 a.m. e-mail, you
2 are copied. You're one of the people that
3 it's sent to down there at the bottom, Cathy
4 Stewart --
5 A. Yes.
6 Q. -- second line.
7 Do you see that?
8 A. Yes.
9 Q. Okay. And did you receive the
10 Federal Registers every day?
11 A. No, I did not.
12 Q. Okay. And then if you go up
13 one to the top of that page, your response,
14 it's April 15, 7:47 a.m., so just a few
15 minutes later.
16 A. Uh-huh.
17 Q. "Karen, if one of those
18 individuals listed in these revocations is a
19 physician of record for one of our clinics,
20 should we halt sales to the clinic? I don't
21 know if we even have a process to monitor and
22 check these revocations against our records.
23 Hopefully Laura can answer the question."
24 Did I read that correctly?
25 A. Yes, you did.

Page 354

1 Q. Okay. And so when it talks
2 about individuals listed in the revocations
3 as being a physician, what are you referring
4 to there?

5 A. Physicians having their DEA
6 registration license revoked so they could no
7 longer write prescriptions for controlled
8 substances.

9 Q. Okay. And that would be a
10 daily update from these Federal Register
11 Notices --

12 A. Yes.

13 Q. -- your understanding?

14 Okay. And so here it looks
15 like you're trying to figure out if there's a
16 way that you all can cross-reference that
17 with the Federal Register Notices.

18 MR. DAVISON: Objection to
19 form.

20 THE WITNESS: Correct. And
21 with our accountants, because the
22 accounts are typically in the clinic's
23 name, not in the physician's name.

24 QUESTIONS BY MS. HERZFELD:

25 Q. Okay.

Page 355

1 A. So we didn't know if Dr. Joe
2 Smith belonged to this clinic or this clinic.

3 Q. Okay. And why would it be
4 important for you to know that?

5 MR. DAVISON: Objection to
6 form.

7 THE WITNESS: Because if we
8 have a doctor who isn't authorized to
9 prescribe or handle controlled
10 substances, we would not want to be
11 shipping them to his clinic.

12 QUESTIONS BY MS. HERZFELD:

13 Q. Okay. And why wouldn't you
14 want to ship it to his clinic?

15 MR. DAVISON: Objection to
16 form.

17 THE WITNESS: Well, it would be
18 against the law for us to do it, for
19 one thing. And number two, if he's
20 doing things that the DEA concludes is
21 not in line with the regulations,
22 then -- and they don't want him
23 dealing with drugs, neither do we.

24 QUESTIONS BY MS. HERZFELD:

25 Q. Okay. And so when you say

Page 356

1 "shipping to a clinic," do you know if those
2 Federal Register Notices -- I'm going to back
3 up.

4 When you say "shipping to a
5 clinic," do you mean clinics where it's --
6 the doctor prescribes it and they dispense it
7 right at that clinic, or do you mean --

8 A. The clinics are methadone
9 clinics.

10 MR. DAVISON: Objection to
11 form.

12 QUESTIONS BY MS. HERZFELD:

13 Q. Okay.

14 A. So drug addicts go there in the
15 morning for their dose of methadone to get
16 them through the day, to try to get them
17 clean.

18 Q. Okay. And is that true for
19 other opioids as well, that the Federal
20 Register Notices were -- would say a license
21 revocation for -- it would be all controlled
22 substances?

23 MR. DAVISON: Objection to
24 form.

25 THE WITNESS: If a doctor's

Page 357

1 license is revoked, it would be for
2 every controlled substance.

3 QUESTIONS BY MS. HERZFELD:

4 Q. Okay.

5 A. Every C-II or C-III, IV, V.

6 I can't think of an instance
7 where he would be restricted from this and,
8 you know --

9 Q. Not that?

10 A. Yeah.

11 Q. Okay. Okay. And so when
12 you're talking about shipping to a clinic,
13 you just told me one example, which would be
14 a methadone clinic; is that right?

15 A. Yes.

16 Q. Okay. What about doctors who
17 had their license suspended but you -- or
18 revoked, their DEA license revoked, and got
19 that notification from the Federal Register
20 but Mallinckrodt wasn't shipping directly to
21 the clinic but instead was shipping to a
22 distributor who was then shipping to that
23 doctor?

24 MR. DAVISON: Objection to
25 form.

Page 358

1 THE WITNESS: It would be
2 incumbent upon that distributor to vet
3 that doctor and determine whether or
4 not they wanted to continue doing
5 business with them.
6 QUESTIONS BY MS. HERZFELD:
7 Q. Okay. So that's not something
8 Mallinckrodt checked?
9 A. No.
10 Q. Okay. Okay. So then flip with
11 me to page 2. And it looks like at the top
12 there's your e-mail again. And you are
13 e-mailing Laura -- how do you say her last
14 name?
15 A. Maher.
16 Q. Maher.
17 And what was her position?
18 A. I think she was in customer
19 data integrity. I'm not positive.
20 Q. Okay. And so in this e-mail
21 you say, "Laura, basically, do you get copies
22 of Federal Register Notices, and do we have a
23 process in place to manage these situations?
24 Even if we sell to direct accounts, should
25 we, question mark?"

Page 359

1 Did I read that correctly?
2 MR. DAVISON: Objection.
3 THE WITNESS: Yes, you did read
4 that correctly.
5 QUESTIONS BY MS. HERZFELD:
6 Q. Okay. And so you're asking a
7 question here to Laura about those Federal
8 Register Notices?
9 A. Uh-huh.
10 Q. And then you say, "Even if we
11 sell to indirect accounts."
12 What's an indirect account?
13 A. To a distributor.
14 Q. So like what we were just
15 talking about?
16 A. Right.
17 Q. Okay.
18 A. Or an AT, an addiction therapy,
19 clinic.
20 Q. Okay. Now flip with me to the
21 first page, if you wouldn't mind, ma'am.
22 A. Okay.
23 Q. Okay. Then at the bottom here,
24 it looks like Laura responds to you April 15,
25 2009.

Page 360

1 Do you see where I'm at?
2 A. Uh-huh.
3 Q. Okay. And she says, "We do not
4 receive any notices. For indirect accounts,
5 whether we close the account or not, does not
6 prohibit the distributor from selling to the
7 customer. We could close the account and let
8 the distributor chargeback group know they
9 cannot cross-reference a sale to the customer
10 due to the issue. The only thing is, can
11 they become compliant again and how would we
12 know? To close any account, all we need to
13 know is the DEA number, if that is easier."
14 Did I read that correctly?
15 A. Yes, you did.
16 Q. Okay. And so then you respond
17 to that and you say, "I'll bring this issue
18 to the next suspicious order monitoring team
19 meeting."
20 Did I read that right?
21 A. Yes, you did.
22 Q. Okay. And did -- oh, I guess
23 actually Karen said that, "Cathy, I will
24 bring that to the next" --
25 A. Oh, yes.

Page 361

1 Q. And then you said "thanks."
2 A. Right.
3 Q. Okay. Do you know if there was
4 a discussion about this issue with physicians
5 and their licenses for indirect accounts that
6 was brought up at the next suspicious order
7 monitoring team meeting?
8 A. I don't know.
9 Q. Do you know if that ever
10 changed, that process?
11 MR. DAVISON: Objection to
12 form.
13 THE WITNESS: I don't know.
14 QUESTIONS BY MS. HERZFELD:
15 Q. Okay. Did it change while you
16 were there?
17 MR. DAVISON: Objection to
18 form.
19 THE WITNESS: Not that I
20 recall.
21 QUESTIONS BY MS. HERZFELD:
22 Q. Okay. Okay. You can set that
23 one aside.
24 (Mallinckrodt-Stewart Exhibit
25 62 marked for identification.)

Page 362

1 QUESTIONS BY MS. HERZFELD:
 2 Q. Okay. I'm handing you what's
 3 been marked as Plaintiff's Exhibit 62.
 4 You'll start with me from the very bottom.
 5 It's really the bottom of the first page
 6 because it's just your signature line after
 7 that.
 8 Okay. So this appears to be an
 9 e-mail sent from your e-mail account to Karen
 10 Harper, copying Jim Rausch, on November 3,
 11 2009, at 7:42 a.m.; is that correct?
 12 A. Huh-uh.
 13 Q. Do you have any reason to think
 14 that that e-mail wasn't sent by you?
 15 A. No.
 16 Q. Okay. And so in this e-mail
 17 you say, "Based on the feedback we got about,
 18 quote, verifying whether or not our
 19 customers' customers have an SOM program in
 20 place, can you confirm whether or not that is
 21 a requirement?"
 22 And then you go on a bit.
 23 And then in response to that,
 24 Karen Harper says, "Cathy, the regulations
 25 only require the registrant, assumed to be us

Page 363

1 in this case, maintain a suspicious order
 2 monitoring program and do not require that we
 3 confirm our customers have a suspicious order
 4 monitoring program."
 5 Did I read that correctly?
 6 A. Yes.
 7 Q. Okay. And was that your
 8 understanding?
 9 MR. DAVISON: Objection to
 10 form.
 11 THE WITNESS: Based on Karen's
 12 explanation here, yes.
 13 QUESTIONS BY MS. HERZFELD:
 14 Q. Okay. And if Karen told you
 15 something was her interpretation of a
 16 particular regulation, did you accept that?
 17 A. Yes.
 18 MR. DAVISON: Objection to
 19 form.
 20 QUESTIONS BY MS. HERZFELD:
 21 Q. Okay. So then she says, "We
 22 added this item to our customer questionnaire
 23 as an enhancement while we were in the throes
 24 of the Sunrise distributor investigation
 25 because we were focusing not only on Sunrise

Page 364

1 but on a physician that was a Sunrise
 2 customer."
 3 Did I read that correctly?
 4 A. Yes, you did.
 5 Q. Okay. "Given that we had a
 6 valid customer challenge on the requirement,
 7 I vote to take it off the checklist."
 8 Did I read that correctly?
 9 A. You did.
 10 Q. Okay. Do you know anything
 11 about who the customer was that challenged
 12 the requirement that the -- that your
 13 customer's customer have a suspicious order
 14 monitoring program?
 15 MR. DAVISON: Objection to
 16 form.
 17 THE WITNESS: I don't recall.
 18 QUESTIONS BY MS. HERZFELD:
 19 Q. Okay. Do you recall being in
 20 any meetings where it was discussed?
 21 A. No.
 22 Q. Okay. And then you said, "I
 23 concur. I'll revise the form."
 24 Did I read that correctly?
 25 A. Yes.

Page 365

1 Q. Okay. And did you indeed
 2 revise the form?
 3 A. I don't know.
 4 Q. Okay. Do you have any reason
 5 to think you wouldn't have?
 6 A. No.
 7 MR. DAVISON: Objection to
 8 form.
 9 (Mallinckrodt-Stewart Exhibit
 10 63 marked for identification.)
 11 QUESTIONS BY MS. HERZFELD:
 12 Q. Okay. Okay. I'm handing you
 13 what we've marked Exhibit 63. Take a look at
 14 it for a second. This is a quick one.
 15 So do you recognize this
 16 e-mail?
 17 A. No.
 18 Q. Okay. Does it appear to be an
 19 e-mail sent from you to Karen Harper on
 20 January 5, 2010?
 21 A. Yes.
 22 Q. Okay. Do you have any reason
 23 to think it wasn't sent from your e-mail
 24 account?
 25 A. No.

Page 366

1 Q. Do you have any reason to think
 2 it wasn't you?
 3 A. No.
 4 Q. Okay. So it says, "Since we're
 5 still in limbo on the formula that's causing
 6 the lion's share of hits in our program, I
 7 asked George if he ever got an update from
 8 Mansfield on a better formula. He's going to
 9 follow up with them."
 10 Did I read that correctly?
 11 A. Yes, you did.
 12 Q. Okay. Who is Mansfield?
 13 A. Mansfield was our corporate
 14 office in Princeton, up in your neck of the
 15 woods.
 16 Q. Okay. Is it a place and not a
 17 person?
 18 A. Mansfield is the town --
 19 Q. Okay.
 20 A. -- or the city that Tyco
 21 International, who originally bought us when
 22 we became Covidien, that was their
 23 headquarters.
 24 Q. Okay. So if I was looking for
 25 a person named Mansfield --

Page 367

1 A. Yeah, you're not going to find
 2 Mansfield, no.
 3 Q. It's a place?
 4 A. It's a place.
 5 Q. Gotcha. Okay.
 6 A. Yeah.
 7 Q. Very good.
 8 It says, "We're still in limbo
 9 on the formula that's causing the lion's
 10 share of the hits in the program."
 11 Do you know what you were
 12 talking about there?
 13 MR. DAVISON: Objection to
 14 form.
 15 THE WITNESS: I don't recall
 16 what formula specifically was causing
 17 the hits.
 18 QUESTIONS BY MS. HERZFELD:
 19 Q. Do you know what the hits were?
 20 MR. DAVISON: Objection to
 21 form.
 22 THE WITNESS: It's speculation.
 23 QUESTIONS BY MS. HERZFELD:
 24 Q. That's okay.
 25 MR. DAVISON: Objection to

Page 368

1 form.
 2 THE WITNESS: I think
 3 reports -- orders that showed up on
 4 the report that maybe shouldn't have.
 5 QUESTIONS BY MS. HERZFELD:
 6 Q. Okay. So when you were saying
 7 "hits," you think there was a -- the formula
 8 was giving you a lot of hits?
 9 A. Yes.
 10 MR. DAVISON: Objection to
 11 form.
 12 QUESTIONS BY MS. HERZFELD:
 13 Q. Okay. And so you asked George
 14 if he ever got an update on a better formula.
 15 A. Right.
 16 Q. Who's George?
 17 A. George was my boss.
 18 Q. Okay. What was George's last
 19 name?
 20 A. Saffold, S-a-f-f-o-l-d.
 21 Q. Okay. And did you deal with
 22 George Saffold at all on changing the formula
 23 for the --
 24 A. No. Actually what we were
 25 doing in this instant {sic} was hoping that

Page 369

1 some of the experts in Mansfield, because
 2 they had statisticians up there, might be
 3 able to help us come up with a more logical
 4 formula.
 5 Q. Okay. Very good.
 6 And do you know if you ever
 7 heard back from anyone on that?
 8 A. I don't know.
 9 MS. HERZFELD: Okay. I don't
 10 think I have any more questions.
 11 THE WITNESS: Thank you.
 12 VIDEOGRAPHER: We are going off
 13 the record at 5:51 p.m.
 14 (Off the record at 5:51 p.m.)
 15 VIDEOGRAPHER: We are back on
 16 the record at 5:56 p.m.
 17 EXAMINATION
 18 QUESTIONS BY MR. GOTTO:
 19 Q. Ms. Stewart, I just want to
 20 follow up -- a couple follow-up questions
 21 concerning Exhibit 62 that you just looked at
 22 with counsel a few moments ago.
 23 I'm looking at your e-mail
 24 that's at the bottom of the first page of
 25 Exhibit 62 --

Page 370

1 A. Yes.

2 Q. -- in which you ask Ms. Harper,

3 "Based on the feedback we got about verifying

4 whether or not our customers' customers have

5 an SOM program in place, can you confirm

6 whether or not that is a requirement?"

7 Correct?

8 A. Correct.

9 Q. So if I understand this

10 correctly, you were asking Ms. Harper whether

11 there was a requirement to determine whether

12 your customer's customer had a suspicious

13 order monitoring program in place, correct?

14 MR. DAVISON: Objection to

15 form.

16 THE WITNESS: Yes, and whether

17 or not that was required from DEA

18 regulations.

19 QUESTIONS BY MR. GOTTO:

20 Q. Okay. And then Ms. Harper

21 responded, "The regulations only require that

22 the registrant, assumed to be us in this

23 case, maintain a suspicious order monitoring

24 program and do not require that we confirm

25 our customers have a suspicious order

Page 371

1 monitoring program."

2 Correct?

3 A. Correct.

4 Q. So did you understand

5 Ms. Harper to be informing you that the DEA

6 regulations did not require determining

7 whether Mallinckrodt's customer had a

8 suspicious order monitoring program in place?

9 A. Correct.

10 MR. DAVISON: Objection to

11 form.

12 THE WITNESS: And she quotes

13 the paragraph of the regulation that

14 she used to assume that.

15 QUESTIONS BY MR. GOTTO:

16 Q. Okay. And did you take that to

17 also mean that there was no requirement -- no

18 DEA requirement that Mallinckrodt take any

19 step to verify whether its customer's

20 customer had a suspicious order monitoring

21 program?

22 MR. DAVISON: Objection to

23 form.

24 THE WITNESS: Correct.

25

Page 372

1 QUESTIONS BY MR. GOTTO:

2 Q. Did you have an understanding,

3 based on information from Ms. Harper or

4 otherwise, with respect to whether

5 Mallinckrodt had any -- any obligation under

6 the DEA regulations to take any steps to

7 monitor the actions that its customers took

8 to guard against diversion of product after

9 those products had been purchased from

10 Mallinckrodt and possession was taken by the

11 customers?

12 MR. DAVISON: Objection to

13 form.

14 THE WITNESS: Can you repeat

15 that?

16 QUESTIONS BY MR. GOTTO:

17 Q. Yes.

18 Did you have any understanding

19 from Ms. Harper or otherwise with respect to

20 whether Mallinckrodt had any obligation under

21 DEA regulations to monitor to any extent

22 what, if any, actions its customers took to

23 prevent the diversion of narcotics that those

24 customers had purchased from Mallinckrodt?

25 MR. DAVISON: Objection to

Page 373

1 form.

2 THE WITNESS: I believe that

3 Mallinckrodt was not obligated, to the

4 letter of the law in that regard, to

5 monitor our -- to see if our customers

6 were monitoring their customers'

7 efforts to avoid diversion.

8 QUESTIONS BY MR. GOTTO:

9 Q. Okay. And as far as you know,

10 in your -- to the extent you participated in

11 suspicious order monitoring by Mallinckrodt,

12 you didn't take any steps to ascertain what,

13 if any, steps Mallinckrodt's customers were

14 taking to guard against diversion of product

15 purchased from Mallinckrodt?

16 MR. DAVISON: Objection to

17 form.

18 THE WITNESS: No, I did not.

19 MR. GOTTO: Okay. I have

20 nothing further.

21 THE WITNESS: Okay.

22 MR. GOTTO: Thank you.

23 MR. DAVISON: I have nothing.

24 MR. GOTTO: Anyone on the call

25 have any questions?

Page 374

1 VIDEOGRAPHER: We are going off
 2 the record at 6 p.m.
 3 (Deposition concluded at 6:00 p.m.)
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Page 376

1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it. You are signing
 10 same subject to the changes you have noted on
 11 the errata sheet, which will be attached to
 12 your deposition.
 13 It is imperative that you return
 14 the original errata sheet to the deposing
 15 attorney within thirty (30) days of receipt
 16 of the deposition transcript by you. If you
 17 fail to do so, the deposition transcript may
 18 be deemed to be accurate and may be used in
 19 court.
 20
 21
 22
 23
 24
 25

Page 375

1 CERTIFICATE
 2
 3 I, CARRIE A. CAMPBELL, Registered
 4 Diplomate Reporter, Certified Realtime
 5 Reporter and Certified Shorthand Reporter, do
 6 hereby certify that prior to the commencement
 7 of the examination, Cathy Stewart was duly
 8 sworn by me to testify to the truth, the
 9 whole truth and nothing but the truth.
 10 I DO FURTHER CERTIFY that the
 11 foregoing is a verbatim transcript of the
 12 testimony as taken stenographically by and
 13 before me at the time, place and on the date
 14 hereinbefore set forth, to the best of my
 15 ability.
 16 I DO FURTHER CERTIFY that I am
 17 neither a relative nor employee nor attorney
 18 nor counsel of any of the parties to this
 19 action, and that I am neither a relative nor
 20 employee of such attorney or counsel, and
 21 that I am not financially interested in the
 22 action.
 23
 24 CARRIE A. CAMPBELL,
 25 NCRA Registered Diplomate Reporter
 Certified Realtime Reporter
 Notary Public
 Dated: December 14, 2018

Page 377

1 ACKNOWLEDGMENT OF DEPONENT
 2
 3
 4 I, _____, do
 5 hereby certify that I have read the foregoing
 6 pages and that the same is a correct
 7 transcription of the answers given by me to
 8 the questions therein propounded, except for
 9 the corrections or changes in form or
 10 substance, if any, noted in the attached
 11 Errata Sheet.
 12
 13 _____
 14 Cathy Stewart DATE
 15
 16 Subscribed and sworn to before me this
 17 _____ day of _____, 20 _____.
 18 My commission expires: _____
 19 Notary Public
 20
 21
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Page 378

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	ERRATA		
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Page 379

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